Supplementary Table 1. Schedule of Events including detail of participant follow-up and assessments.

Assessment/Activity	**Pre-screening (Referral Pathway 1)**	**Pre-Screening (Referral Pathway 2)**	**Trial Information**	**Screening/ Baseline**	**IMP Receipt Check**	**Follow-up 1**	**Follow-up 2**	**Follow-up 3**	**Follow-up 4**
Contact type[1]	**No patient contact**	**Patient contact in clinic**	**Telephone call**	**Telephone call**	**Telephone call**	**Remote (ePRO)**	**Remote (ePRO)**	**Remote (ePRO)**	**Clinic visit[6]**
					Within 3 days (+/- 2 days) of IMP shipment	**2 weeks (+7 days) after 1st dose of IMP**	**4 weeks (+7 days) after 1st dose of IMP**	**6 weeks (+7 days) after 1st dose of IMP**	**8 weeks (-6 /+14 days) after 1st dose of IMP**
Identification of potential patients for TALGiTS	X	X							
First patient contact; verbal explanation of trial and PIS sent to patients expressing interest		X	X						
Written Informed Consent[2]				X					
Head and Neck risk calculator[6]				X					
Demographics, medical history, medication history				X					
Reflux Symptom Index (RSI) Questionnaire				X		X	X	X	X
Comprehensive Reflux Symptom Score (CReSS) Questionnaire				X		X	X	X	X
Eligibility assessment[3]				X					

Assessment/Activity	**Pre-screening (Referral Pathway 1)**	**Pre-Screening (Referral Pathway 2)**	**Trial Information**	**Screening/ Baseline**	**IMP Receipt Check**	**Follow-up 1**	**Follow-up 2**	**Follow-up 3**	**Follow-up 4**
Contact type[1]	**No patient contact**	**Patient contact in clinic**	**Telephone call**	**Telephone call**	**Telephone call**	**Remote (ePRO)**	**Remote (ePRO)**	**Remote (ePRO)**	**Clinic visit[6]**
					Within 3 days (+/- 2 days) of IMP shipment	**2 weeks (+7 days) after 1st dose of IMP**	**4 weeks (+7 days) after 1st dose of IMP**	**6 weeks (+7 days) after 1st dose of IMP**	**8 weeks (-6 /+14 days) after 1st dose of IMP**
Randomisation				X					
IMP Order Form completed and sent to Central Distribution Centre (CDC)				X					
IMP shipment to participant[4]				X					
Confirmation of IMP receipt and treatment start date[5]					X				
Concomitant medication						X	X	X	X
Adverse Event reporting				X		X	X	X	X
End of trial questions									X
Participant reported IMP compliance						X	X	X	X
ENT Diagnosis									X[7]

[1] Patients should be encouraged to complete Follow-up 4 as a clinic visit wherever possible for referral pathway 1. At other time points and follow-up 4 for referral pathway 2 the contact type is a recommendation only, contact type can be tailored to the patient's requirements, for example (but not limited to) patients who would prefer face to face visits can be offered a clinic visit, or email or text message contact may be used following local Trust policies and procedures.

[2] Details of the participants consent will be documented on the NCTU consent notification proforma, a copy of the completed proforma will be sent securely (i.e. nhs.net to nhs.net or encrypted email) to the nctu.talgits.conf@nhs.net email address **within 5 working days** of the date of consent. No personal identifiable data will be recorded on the NCTU consent pro-forma.

[3] A copy of the Eligibility Checklist will be sent securely (i.e., nhs.net to nhs.net or encrypted email) to the nctu.talgits.conf@nhs.net email address **within 5 working days** of the date of completion. No personal identifiable data will be recorded on the Eligibility Checklist.

[4] IMP shipment to participants is fulfilled by the CDC.

[5] Treatment start date must be within 4 weeks of receipt of IMP.

[6] Head and neck risk calculator only required to be completed for those participants that have not been assessed clinically at a face-to-face appointment.

[7] ENT diagnosis will only be required for participants on referral pathway 1

Trial of Alginates in Throat Symptoms

TALGiTS
TRIAL OF ALGINATES IN THROAT SYMPTOMS

Mae'r ddogfen yma hefyd ar gael yn Gymraeg / This document is also available in Welsh

Participant Information Sheet

INVITATION

We are inviting you to take part in our research trial called TALGiTS. This is because your GP has referred you to an Ear Nose Throat (ENT) or Speech and Language Therapy (SaLT) department, or you have had an appointment with an ENT or SaLT department, because of your throat symptoms, we call these persistent throat symptoms (PTS).

Please take the time to read the following information carefully to help you decide whether you would like to take part in the trial. We would like you to understand why this research is being carried out and what it would involve for you if you were to take part.

You don't have to decide straight away, and you can discuss this trial with your friends and family or GP. A member of our team will go through this information sheet with you and answer any questions you may have.

The trial is being funded by a company called Reckitt, this is the company who make Gaviscon Advance as well as other medicines. The Newcastle upon Tyne Hospitals NHS Foundation Trust has overall responsibility for the trial, they are known as the trial Sponsor.

TRIAL SUMMARY

- This trial is looking at the use of Gaviscon Advance in comparison to placebo (a 'dummy' treatment) as a potential treatment for persistent throat symptoms.

- Participants will take part in this trial for 8 weeks either between their GP referral to ENT or SaLT departments and their first appointment or following their first appointment with these departments.

- It has been considered for many years that Gastroesophageal Reflux Disease (GORD) could be an underlying cause of persistent throat symptoms. In GORD the contents of the stomach enter the oesophagus (also called the gullet), which runs from the stomach to the throat, and irritate it.

- Gaviscon Advance is a liquid alginate belonging to a group of medicines called "reflux suppressants". Gaviscon Advance forms a protective layer that floats on top of the stomach contents. This layer prevents the stomach contents entering the oesophagus and irritating it.

- Trial participants are assigned randomly by a computer to receive either Gaviscon Advance or a placebo (a 'dummy' treatment). There is an equal chance that you will receive either trial treatments, which will be identical bottles of liquid with the same consistency and taste. You, the hospital trial team and the trial management team will not know which treatment you are receiving.

  Trial medication will be sent to you by courier from a Central Distribution Centre. A member of the hospital trial team will contact you 3-5 days after the expected delivery date of the trial medication to make sure that it has been received and to confirm the date that medication started being taken.

- The trial lasts for 8 weeks from the start of the medication. During the 8 weeks you will take one 10ml dose of their trial medication four times a day;

three times after meals/snacks and one time before bed. A plastic measuring cup will be provided with the medication.

The intention is to run this trial with as much remote contact as possible using telephone, video consultations or any other suitable methods of contact. If you have not already had a clinic appointment one will be planned at the end of the trial, which is the standard clinic appointment you would have received following your referral. However, if you would prefer a different method of contact than the planned, this can be arranged with the hospital trial team. If you have already been seen in clinic before agreeing to take part in the TALGiTS trial, you may not be seen again in clinic at the end of the trial, you may have follow-up at the end of the trial remotely.

- You will be asked to complete questionnaires approximately every 2 weeks throughout the 8 weeks of the trial. These will be completed remotely by using your smart phone, computer, laptop or tablet wherever possible. Other methods of completion (e.g. telephone call or paper documents) can be discussed with the hospital trial team if preferred. Invitations to complete questionnaires will be sent by email, please remember to check your junk mail if you do not get these when expected.

- It is important that throughout the 8 week treatment period you do not take any other over the counter antacids and/or alginate products (for example Rennies, Milk of Magnesia or other types of Gaviscon liquid or tablet). If you are unsure that any products you plan to take may be antacids or contain alginates, please contact your local study team to confirm.

- A summary of your potential involvement in the trial is given in Table 2 on page 4 and 5.

Table 2 Overview of what is involved in taking part in the trial **if you have not been seen in clinic already**

Timeline	Activity	Location	What will happen
Next few days	Trial information discussion	Home (remote)	A researcher will contact you by telephone or video call. You will be given information about the trial and can ask the researcher questions
Within 1-2 weeks	Checks and consent	Home (remote)	A researcher contacts you by telephone or video call to make sure that you are safe to enter the trial. You give consent to enter the trial. You complete questionnaires and provide information about you and your symptoms
TRIAL START (usually about three weeks from now)	Trial start	Home (remote)	You are sent the trial medications and one of the research team contacts you to make sure that you have received it and ask the date you started taking the trial medication
2 weeks after trial start	Follow up	Home (remote)	You receive a link to complete questionnaires online and provide information online about your symptoms and how you are getting on. No researcher will contact you for this
4 weeks after trial start	Follow up	Home (remote)	You receive a link to complete questionnaires online and provide information online about your symptoms and how you are getting on. No researcher will contact you for this
6 weeks after trial start	Follow up	Home (remote)	You receive a link to complete questionnaires online and provide information online about your symptoms and how you are getting on. No researcher will contact you for this
8 weeks after trial start	Trial end	Hospital appointment	You attend the hospital to see a healthcare professional about your symptoms. This is like a normal hospital appointment. Here, you will be examined and your treatment options will be discussed. . You complete the last set of questionnaires for the trial

IRAS: 1006014 | TALGiTS | Patient Information Sheet | V3.0| 5th June 2023-Updated Footer

Table 2 Overview of what is involved in taking part in the trial **<u>if you have been seen in clinic already</u>**

Timeline	Activity	Location	What will happen
At clinic appointment	Trial information discussion	Clinic	A researcher will give you information about the trial and can ask the researcher questions
Within 1-2 weeks	Checks and consent	Home (remote)	A researcher contacts you by telephone or video call to make sure that you are safe to enter the trial. You give consent to enter the trial. You complete questionnaires and provide information about you and your symptoms
TRIAL START (usually about three weeks from now)	Trial start	Home (remote)	You are sent the trial medications and one of the research team contacts you to make sure that you have received it and ask the date you started taking the trial medication
2 weeks after trial start	Follow up	Home (remote)	You receive a link to complete questionnaires online and provide information online about your symptoms and how you are getting on. No researcher will contact you for this
4 weeks after trial start	Follow up	Home (remote)	You receive a link to complete questionnaires online and provide information online about your symptoms and how you are getting on. No researcher will contact you for this
6 weeks after trial start	Follow up	Home (remote)	You receive a link to complete questionnaires online and provide information online about your symptoms and how you are getting on. No researcher will contact you for this
8 weeks after trial start	Trial end	Home (remote)	You receive a link to complete questionnaires online and provide information online about your symptoms and how you are getting on. No researcher will contact you for this

Please read the following information for further details about the trial if you are interested in taking part.

Newcastle University

Print on Trust headed paper

WHY IS TALGiTS NEEDED?

Persistent throat symptoms (these include hoarse voice, sore throat, feeling of a lump in the throat, throat clearing, mucus going from the nose into the throat and/ or catarrh [a build-up of mucus]) are very common. At least 60,000 new patients are referred to NHS Ear Nose and Throat (ENT) and/or Speech and Language Therapy (SaLT) departments each year in the UK

For a long time, specialists in the field have thought that persistent throat symptoms can be linked to gastroesophageal reflux disease (GORD). GORD happens when the stomach contents (including stomach acid) frequently flow into the oesophagus (or gullet) which connects the mouth to the stomach, the result of this is that the lining of the oesophagus can become irritated and cause people to have symptoms. One way to treat GORD is by using a liquid alginate, a gloopy substance made from special seaweed, which forms a floating raft on the top of stomach contents and stops them going into the oesophagus to cause irritation.

In this trial we are looking at whether Gaviscon Advance, a liquid alginate, is effective in treating persistent throat symptoms.

This research team recently conducted a similar trial, assessing whether medication that reduces stomach acid improves persistent throat symptoms. The trial showed that these very commonly used medications were no better than a placebo (dummy tablet). There is a real need to help identify how persistent throat symptoms can be treated effectively. Stomach acid reduction medication and Gaviscon Advance both treat GORD effectively, and both work in a very different way to reduce heartburn type symptoms. This research is very important so the NHS can better treat patients with these symptoms in the future.

WHY AM I BEING INVITED TO TAKE PART?

You are being invited to take part in this trial because you have been referred to, or been seen in, an Ear, Nose and Throat (ENT) or Speech and Language Therapy (SaLT) department for persistent throat symptoms.

DO I HAVE TO TAKE PART?

No, it is up to you to decide whether you want to join the trial. If you agree to take part, we will ask you to complete a consent form. If you choose not to, you will continue to get the standard care arranged by your doctor.

If you agree to take part, you can change your mind at any time. You can stop taking the trial medication and carry on with the questionnaires, or you can withdraw from the trial completely. You do not have to give a reason, but it is helpful to the trial if you do, so that ways it can be improved can be understood. If you decide to withdraw completely, data collected up to this point will be retained for analysis. This will not affect the care that you receive.

WHAT WILL GIVING CONSENT MEAN FOR ME?

By signing a consent form, either electronically or handwritten, you are confirming that you fully understand what taking part in the trial means for you. It is important that you carefully consider participating in TALGiTS and take as much time as you need to read this information sheet and ask as many questions as you need to before giving your consent to take part.

WHAT WOULD TAKING PART INVOLVE?

Trial visits/follow-ups

We will ask you to complete several parts of the trial over an 8 week period. An overview is given in Table 2 on page 7, further information is given below:

- *Trial information discussion* – this will be with a member of the hospital trial team. It will take place remotely (for example telephone call or video call) wherever possible but may take place in clinic.
- *Initial checks and consent* – this will be with a member of the hospital trial team. It will take place remotely (for example by telephone call or video call) wherever possible. The team will ensure you are safe to enter the trial. Some people with certain heath complaints or on certain medication may not be eligible to enter the trial. Consent will be taken, ideally using a remote method to record it.
- *Contact to confirm receipt of trial medication* – this will be a remote contact (for example telephone, email) from a member of the hospital trial team

- *2 week follow-up (2 weeks after starting trial medication)* –you will be sent a link to complete the trial questionnaires and information online without contact from a member of the hospital trial team
- *4 week follow-up (4 weeks after starting trial medication)* – you will be sent a link to complete the trial questionnaires and information online without contact from a member of the hospital trial team
- *6 week follow-up (6 weeks after starting trial medication)* – you will be sent a link to complete the trial questionnaires and information online without contact from a member of the hospital trial team
- *8 week follow-up (8 weeks after starting trial medication)* – this will be an in-person appointment at your trial hospital with a member of the hospital trial team if you have not already been seen in clinic. If you have already had an appointment at an ENT or SaLT department, you will be sent a link to complete the trial questionnaires and information online or have them sent to you by post without contact from a member of the hospital trial team, unless you prefer to have a face to face visit.

As described above, most visits/follow-ups for the trial are intended to be completed remotely with one in-person visit at 8 weeks if you have not already been seen in clinic. Should you prefer an alternative way of completing visits/follow-ups (for example, instead of remote you would like to go into clinic in person) this can be arranged for you. In particular for the initial trial discussion and consent part of the trial.

These trial visits/follow-ups are not part of your standard care (i.e. the visits that would take place following your referral if you were not involved in the trial) but the 8 week follow-up, in-person clinic visit, will be your standard care visit if you haven't already been seen in clinic. Taking part in the trial will not affect your standard care visit at 8 weeks, unless your symptoms do improve, and you decide you would rather not attend the clinic in person. Waiting for 8 weeks for the standard care visit is the typical usual wait for these types of appointments. The diagram on page 13 shows the details of the trial hospital visits and what will take place at each visit.

After you have considered the trial, and if you decide to take part, you will attend an initial checks and consent remote consultation, or an in person visit if you

prefer, to check that it is safe for you to enter the trial. You will be asked to consent to taking part in the trial. If you are having a remote consultation, you will be sent a link to your email address to electronically complete and sign the consent form. If you are attending in person, you will complete the consent form in writing.

After consent, a trial doctor will ask you questions about your symptoms, any other problems with your health, any medication that you may be taking and other important questions to make sure that it is safe for you to go into the trial. The trial doctor will ask about your symptoms and complete a cancer risk calculator using your answers; this is to ensure that your throat symptoms do not suggest a possible cancer. If the risk is shown as high, you will not enter the trial and you will have an urgent appointment to investigate your symptoms further.

If your sex at birth is female the trial doctor will ask if you are pregnant. If you are pregnant, you will not be able to take part in the trial. This is because Gaviscon is widely used to treat heartburn associated with pregnancy but in the trial, you have a 50% chance of getting a placebo (or 'dummy' drug) medication which might mean that you don't get the treatment that you need. The trial doctor will confirm with you if you are able to take part in the trial or not.

You will be asked to complete questionnaires at the initial checks and consent consultation and then every 2 weeks after starting to take your trial medication. These will be completed remotely, without contact from the hospital trial team, by using your smart phone, computer, laptop or tablet. You will be asked to provide an email address that you are happy for us to send a link to the questionnaires to. If you forget to complete a questionnaire a reminder will be sent to your email address as a prompt. After 7 days the questionnaire will no longer be available for completion. If you do not wish to complete these questionnaires electronically you may either have a telephone consultation with the hospital trial team to dictate your answers, or paper copies may be completed by post or at in person visits if you have chosen to have these. We estimate that the questionnaires will take 10 minutes to complete.

At the same time that you complete trial questionnaires, you will be asked to record any side effects that you experience while taking the trial medication and any changes to any of your non trial medications. You will be asked to record how much of the medication you have used at each follow up.

At the final trial follow-up (8 week follow-up) you will be asked to rate your experience of taking part in the trial by a specific questionnaire. You will also be asked whether you think that you have been taking Gaviscon Advance or placebo. You won't find out which treatment you have received during the trial.

WHAT TREATMENT WOULD I BE ON?

You will be randomly assigned by a computer to take one of two trial medications:

- Gaviscon Advance
- Placebo

You will have a 50% chance of being assigned to Gaviscon Advance and a 50% chance of being assigned to placebo. This trial is double-blind. This means that you, the hospital trial team and the people who manage the trial will not know which treatment you are receiving.

Gaviscon contains 1000mg sodium alginate and 200mg potassium hydrogen bicarbonate. The placebo does not contain any of these ingredients.

It is important that during the 8 week treatment period that you do not take any over the counter Gaviscon, alginate products or antacids in any form (liquid or table).

Both trial medications will be identical bottles of liquid. The liquid for both trial medications have the same consistency and taste so that we don't know which medication is which.

The hospital trial team will make arrangements with you for the trial medication to be delivered to you by a courier. It is very important that you can take delivery of the trial medication. If you are usually not at home during the day you can have the medication delivered to a different address or nominate someone else at your household to take receipt of the medication on your behalf. The courier will contact you on the day of delivery with an expected delivery window and will never request any payment details from you. You will receive one shipment of trial medication which will contain 10 bottles, this is enough for the 8 week trial period and some extra in case it is needed (for example if a bottle breaks). A member of

Morton M, *et al. BMJ Open* 2025; 15:e087729. doi: 10.1136/bmjopen-2024-087729

the trial team will call you 3-5 days after the expected delivery date of the medication to make sure that you have received your medication and to confirm the date that you started taking your medication.

You will take 10 millilitres (mls) of your trial medication, using the measuring cup supplied, 4 times a day; one dose after each meal and one dose before bed. You will take the medication every day for the 8 weeks of the trial. If you have a different eating pattern, or miss a meal, we would suggest you take the medication after any snack or at an appropriate interval between the other doses you take that day.

You will be asked to record how much medication you have left in each bottle electronically when you complete your trial questionnaires at 2, 4, 6 and 8 weeks after starting the trial medication.

After the last visit for the trial (week 8 follow-up) you will be able to dispose of your trial medication by taking them to your nearest community (i.e. not a hospital) pharmacy.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You may not experience any direct benefit from taking part in this trial, though it could be that the trial medication may have an effect on your persistent throat symptoms. The information we get from this trial may help to manage the care of people with persistent throat symptoms in the future.

EXPENSES

There are no expenses anticipated as part of the trial.

WILL MY GP KNOW THAT I'M TAKING PART IN THE TRIAL?

Yes, we will send a letter to your GP to inform them that you are taking part in this trial, and a copy will be filed in your hospital medical records. You will be asked to consent to your GP being informed. This is so that your medical records at your GP practice and in hospital contain documentation that you are taking part in a clinical trial.

Your GP will not know if you have received Gaviscon Advance or placebo (the 'dummy' drug) as your trial medication.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Gaviscon Advance is used widely and has well understood side effects. Most people who take Gaviscon Advance do not have any side effects. However, as with all medications side effects can occur, these are likely to be mild and will go away when Gaviscon Advance is stopped. The known side effects of Gaviscon Advance are listed in the table below.

Frequency	Side Effect
Very Rare (less than 1 in 10,000 people)	Anaphylaxis Hypersensitivity reactions such as urticaria (a red bumpy skin rash)
Very Rare (less than 1 in 10,000 people)	Respiratory effects such as bronchospasm (tightening and narrowing of the airways)

You could be assigned to receive the placebo 'dummy' trial medication. This has no active ingredient. You and the hospital trial team will not know which trial medication you are taking.

PREGNANCY AND BREAST FEEDING

If you are known to be pregnant you will not be able to take part in the trial. This is because Gaviscon is widely used to treat heartburn associated with pregnancy but in the trial, you have a 50% chance of getting a placebo (or 'dummy' drug) which might mean that you don't get the treatment that you need.

If you become pregnant whilst taking part in the trial you will be able to remain in the trial, if you wish to do so, but you will need to notify the hospital trial team of your pregnancy. Gaviscon Advance is safe to use in pregnancy. The reason you can stay on the trial if you become pregnant on the trial is that it is unlikely that at the early stages of pregnancy that you would experience pregnancy associated heartburn. As the trial lasts for 8 weeks your participation would likely be complete before the stage of pregnancy where heartburn is experienced. You should discuss any symptoms you have with your hospital trial team.

You will still be able to take part in the trial if you are breastfeeding. Gaviscon Advance is safe to take while breastfeeding.

WHAT WILL HAPPEN TO ME WHEN THE TRIAL ENDS?

You will stop taking the trial medication at the end of 8 weeks. You will continue to receive standard care like any other patient referred to ENT or SaLT departments due to persistent throat symptoms. You and your ENT or SaLT doctor(s) can discuss which treatment would be best for you going forward. You and your doctors will not find out which trial medication you were taking during the trial.

WHAT IF SOMETHING GOES WRONG?

If you have a concern about any aspect of this trial, you can speak to a member of the trial team who will do their best to answer your questions. Further contact details are included at the end of this information sheet. If you are still unhappy and wish to raise your concerns with someone who is not directly involved in your care, you can contact <site to localise with local details such as PALS (or equivalent) phone number and email address>

In the unlikely event that you are harmed during the trial, and this is due to someone's negligence (they were careless) you may have grounds for legal action and compensation, but you may need to meet your own legal costs. NHS Indemnity does not offer no-fault compensation (for harm that is not anyone's fault).

The Newcastle Clinical Trials Unit, part of Newcastle University, are managing the trial on behalf of the trial NHS Sponsor. Newcastle University also have insurance arrangements in place to cover Newcastle University staff involved in designing and managing the TALGiTS trial.

WHO IS ORGANISING AND FUNDING THE TRIAL?

The doctor in charge of the trial (the Chief Investigator) is Mr James O'Hara, a Consultant ENT Surgeon. He is based in Newcastle upon Tyne.

Trial Sponsor: The Newcastle upon Tyne Hospitals NHS Foundation Trust. The trial Sponsor has responsibility for the trial. The trial is managed by the Newcastle Clinical Trials Unit, Newcastle University, on behalf of the Sponsor.

Trial Funder: Reckitt, a pharmaceutical company who make Gaviscon Advance.

WHO HAS REVIEWED THIS TRIAL?

This trial was reviewed and approved by the Research Ethics Committee East Midlands – Leicester South Research Ethics Committee, the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA are responsible for approving all trials involving medicines. The Newcastle Upon Tyne Hospitals NHS Foundation Trust has reviewed all the trial documentation and assessed the risks of this trial as part of their responsibility, as trial Sponsor. This is to ensure that we are not doing anything harmful to you during the trial and that your data is collected safely and stored securely. ENT & SaLT patients have reviewed this trial and the documents that participants are given.

WHO IS PROVIDING THE TRIAL MEDICATION?

Gaviscon Advance and placebo will be provided by Reckitt, a pharmaceutical company. A Central Distribution Centre (CDC) will store the trial medication and arrange delivery of trial medication to participants. The CDC will arrange a courier to deliver your trial medication. The courier may contact you by text message or email to confirm delivery. The courier company will never ask you for personal details or for any kind of payment. If you are worried that a message/email is not genuine, please contact your local trial team to talk about it.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

If new information becomes available during the trial that is relevant to you, we will tell you about it. We will discuss whether you should or would like to stop the trial treatment or withdraw from the trial.

WHAT WILL HAPPEN TO THE RESULTS OF THE TRIAL?

- The results will be written in medical journals and presented in meetings to other doctors, nurses, researchers and patients.
- All trial data that is published will be anonymous. Your identity will always be protected.

Morton M, *et al. BMJ Open* 2025; 15:e087729. doi: 10.1136/bmjopen-2024-087729

- The results will be available at the end of the trial through publications, in the wider press and directly to patient groups. You will be able to read the result on the website or request a copy of the summary of the results from your trial hospital.
- Fully de-identified data may be made available to other researchers to help inform other research studies.

WILL MY TAKING PART IN THIS TRIAL BE KEPT CONFIDENTIAL?

Yes. All the information collected in the trial will be entered on computers that are kept secure and password protected, and any identifiable information transferred will be encrypted.

- You will be given a unique trial number (called a Subject Identification Number) which will be used instead of your name being written on trial documents. The trial team at your hospital will be able to link this number back to you using your date of birth, name, and NHS number (or other nations equivalent)
- The trial team at your hospital will have access to your information (name, address, telephone number and email address) during the trial to contact you.
- You will be asked to consent to a letter being sent to your GP to inform them that you are taking part in this trial.
- The Central Distribution Centre and their designated courier will have access to your name, address and contact details for delivering your trial medication
- Your contact details will never be shared with anyone outside of the trial with the exception of the Central Distribution Centre and their designated courier. You will be asked to consent to the Central Distribution Centre and their designated courier to have access to your contact details so that they can arrange delivery of your trial medication to your nominated address. The courier used by the Central Distribution Centre will not know that you are taking part in the trial, just that they need to deliver a package to you
- Your email address and mobile phone number (if you provide a mobile number) will be stored in a central study database so that we can send the

links to the consent form and questionnaires to you. These details will be encrypted and only accessible to your local hospital trial team.

- You will not be named in any results, reports or on websites
- Very occasionally, information might be given during the trial that we would have a legal obligation to pass on to others (for instance information which suggested you or others were at risk of harm). In this case, confidentiality would be broken so that we could pass this information to the relevant people. You would be informed of this
- At the end of the trial, all trial information will be kept in a secure storage area (this is called archiving) for at least 5 years. This makes sure any queries about the running of the trial have been answered. All information will be held securely to make sure we protect your confidentiality, after which it will be safely destroyed
- If there are any serious adverse events, we would send details of them to the government medicines agency (MHRA); only your Subject ID number would be sent to them not your name. This information may also be sent to researchers outside of the United Kingdom (UK) in the European Economic Area (EEA) who are involved in overseeing the trial.
- Some parts of your medical records and the data collected for the trial may be looked at by authorised persons from the MHRA, Sponsor (Newcastle Hospitals NHS Foundation Trust) and or the Newcastle Clinical Trials Unit to check that the trial is being conducted to the correct standards. All will have a duty of confidentiality to you as a research participant.

HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you, from your medical records and from your GP record for this trial.

This information will include your initials, date of birth, sex at birth, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will share your full name, address and contact details with a third party Central Distribution Centre and their designated courier so that the trial medication can be delivered to you. We will only transfer the minimum amount of information about you required to arrange delivery.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number, your unique Subject ID, instead.

At the end of your trial participation the final diagnosis for your throat symptoms will be recorded in a database however this will not be linked to you directly but to your unique Study ID instead.

We will keep all information about you safe and secure.

Once we have finished the trial, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the trial.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

- You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from https://www.newcastle-hospitals.nhs.uk/help/privacy/privacy-notice-for-patients/

- by asking one of the research team
- by sending an email to the Sponsor Data Protection Officer at nuth.dpo@nhs.net
- by calling The Newcastle upon Tyne Hospitals NHS Foundation Trust Data Protection Officer on 0191 223 1474

FURTHER INFORMATION AND CONTACT DETAILS

If you have any further questions or would like any further information about the trial or the rights of participants, please feel free to contact the people below.

They are also who you or your doctor(s) should contact in the event of an emergency, if your trial participation is in any way involved.

[LOCAL CONTACT DETAILS]

Thank you for reading this information sheet.

Newcastle University

Print on Trust headed paper

TALGiTS
TRIAL OF ALGINATES IN THROAT SYMPTOMS

INFORMED CONSENT FORM

V2.0, 1st March 2023

Trial Subject ID: | | | | | | |

Principal Investigator: _____

Please INITIAL the boxes if

1.	I confirm that I have read the Participant Information Sheet dated __ __ /__ __ _ /__ __ __ __ version ___ for the TALGiTS trial and that I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3.	I consent to receiving the trial medication outlined in the Participant Information Sheet.	
4.	I understand that my personal data (name, address, telephone number and email address) will be used for the purposes of shipping trial medication to my home address and for contacting me. I give permission for this information to be stored by responsible people at my local NHS Trust and on the central trial database (Sealed Envelope's Red Pill [Sealed Envelope Ltd, London, UK]) and for them to be accessed by Central Distribution Centre staff, or any courier service used by the Central Distribution Centre, so that the trial medication can be shipped to my home address.	
5.	I understand that information about me that is relevant to this trial will leave my local NHS Trust and be stored in a central trial database managed by Newcastle University. This includes my date of birth, sex at birth and ethnicity which will be stored on the	

	central trial database. I understand that my data will be stored securely and managed confidentially as part of this trial.	
6.	I understand that any personal information collected about me for the trial will be kept confidential and not be made public. I understand that data from the trial will be published in medical journals, at research meetings and shared with other researchers, including researchers potentially outside the United Kingdom (UK) in the European Economic Area (EEA). I understand that data from the trial will be de-identified and that I will not be directly identified in the published results.	
7.	I consent to receive trial notifications and reminders to complete questionnaires via email, text message, telephone call or post. I understand that my email address and/or mobile telephone number will be stored in the central trial database so that notifications and reminders can be sent to me and that this personal information will be encrypted and only accessible by responsible people at my local NHS Trust .	
8.	I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researcher projects and researchers.	
9.	I understand that parts of my medical records and data collected during the trial may be looked at by responsible people. I give my permission for these people to have access to my medical records. This includes people from Newcastle University, the trial Sponsor, regulatory authorities and local NHS Trust, where it is relevant to my taking part in research.	
10.	I understand that the information provided in this trial is being managed by the Newcastle Clinical Trials Unit, which is part of Newcastle University.	
11.	I agree to my General Practitioner being notified of my involvement in the trial, including any necessary exchange of information about me between my GP and the research team	
12.	I agree to the information provided and this signed consent form being stored for 5 years after the end of the trial.	
13.	I agree to take part in the TALGiTS trial.	

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

(Original to be filed in the ISF, 1 copy to be given to participant and 1 copy to be filed in patient medical records)

Morton M, *et al. BMJ Open* 2025; 15:e087729. doi: 10.1136/bmjopen-2024-087729