Hôpitaux Universitaires Genève

Neurosurgery Department

Application to participate in a medical research project:

Middle Meningeal Artery Embolization for Chronic Subdural Hematomas: A Randomized Clinical Trial to Determine the Likelihood of Recurrence After Embolization

Dear Madam, Sir,

The patient, the person under your responsibility, has been included in a clinical trial in an emergency situation. In all likelihood, he/she will remain permanently incapable of discernment and, therefore, of communicating his/her will. Insofar as you represent him/her as a relative or legal representative, we send you this document to inform you about our study. In addition, we ask you to give us your consent to participate in the project retroactively and in your capacity as a relative or legal representative.

Below we present the project to you: first, with a summary to give you a quick overview, then with a more detailed description.

Al Awadhi A, *et al. BMJ Open* 2025; 15:e092014. doi: 10.1136/bmjopen-2024-092014

Application to participate in a medical research project:

Middle Meningeal Artery Embolization for Chronic Subdural Hematomas: A Randomized Clinical Trial to Determine the Likelihood of Recurrence After Embolization

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Dear Madam, Sir,

We propose here that you give us your consent for the patient's participation in our project.

Participation is completely free. All data collected in this project is subject to strict data protection rules.

The research project is led by Prof. Karl Schaller. We will communicate the results to you if you wish.

In an interview, we will walk you through the essentials and answer your questions. To give you an overview of the project, here are the key points to remember. You will find more detailed additional information below.

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Application to participate in medical research

Study title: Middle meningeal artery embolization for chronic subdural hematomas: a randomized clinical trial to determine the likelihood of recurrence after embolization

Simplified title: STORMM

Dear Madam, Sir,

We would like to introduce you to STORMM and invite you to participate. Before a new intervention method can be applied by doctors, research is indeed needed to find out how this intervention method works.

In medicine, such research is called a **clinical study**. In this study, we want to evaluate whether the efficacy of middle meningeal artery embolization in the recurrence of subdural hematomas is good/equivalent or superior compared to conventional radio-clinical follow-up. We also want to evaluate whether this new treatment can be beneficial for patients in whom surgical treatment is contraindicated. That's why we're asking if you'd like to participate in this study.

Your participation is voluntary. This **information form** should help you make your decision. You can ask all your questions during an **interview with the investigating physician**. This person is responsible for monitoring the participants in the study. If you agree to participate in the study, please sign the **consent statement** at the end of the document. By signing it, you certify that you have read and understood the information provided. If you don't understand something, don't hesitate to ask the investigator/investigator for clarification

The information and consent form consists of four parts:

Part 1 **The Essentials in a Nutshell**
Part 2 **Detailed information on the study**
Part 3 **Data Protection and Insurance Coverage**
Part 4 **Declaration of Consent**

In **Part 1**, you will get a general overview of the study. In **Part 2**, we explain in detail the process and context of the study. Part **3** contains information on data protection and insurance coverage. By signing the consent at the end of the document, **Part 4**, you certify that you have understood all the information and agree to participate.

This study is initiated by the University Hospitals of Geneva This institution is called the sponsor. The sponsor assumes responsibility, management and funding for a study.

The reference persons for this study are:

Name Prof. Karl Schaller, Head of Department
Address Neurosurgery Department
Department of Clinical Neurosciences
HUG
Rue Gabriel-Perret-Gentil, 4
1211 Geneva 14
Telephone +41 (0)22 372 82 02
+41 795533810 Neurosurgery On-call (available 24 hours a day)
Email Karl.Schaller@hcuge.ch

Name Dr Aria Nouri
Address Neurosurgery Department
Department of Clinical Neurosciences
HUG
Rue Gabriel-Perret-Gentil, 4
1211 Geneva 14
Telephone +41 (0)79 553 09 58
Email Aria.Nouri@hcuge.ch

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Part 1: The essentials in a Nutshell

1. Why are we conducting this study?

In the presence of symptomatic subdural hematomas (accumulation of blood), the standard treatment consists of surgical evacuation of the hematoma, with the aim of avoiding serious sequelae and allowing maximum neurological recovery. However, a recurrence of these hematomas is often observed. Recent studies suggest that embolization (obstruction) of the middle meningeal artery (the artery that promotes this bleeding) in addition to surgical evacuation of the hematoma may limit the recurrence of the hematoma.

In this study, we will investigate the efficacy of middle meningeal artery embolization in the recurrence of subdural hematomas. We also want to evaluate whether this new treatment could be beneficial for patients in whom surgical treatment is contraindicated. You will learn more about the scientific background of the study in **Chapter 4**.

2. What do you have to do if you participate?

For patients in whom surgical treatment allowing the evacuation of the hematoma is indicated: If you agree to participate in our project, you will be randomly assigned after the surgical treatment either to a group of patients who will benefit from the embolization of the middle meningeal artery, or to a group of patients who will benefit from a classic radio-clinical follow-up.

For patients in whom surgical treatment to evacuate the hematoma is contraindicated or who refuse surgical treatment: If you agree to participate in our project, you can either benefit from embolization of the middle meningeal artery, or benefit from standard follow-up if you do not wish to receive embolization treatment.

Procedure for all participants: After the treatment, all patients will be followed for 6 months. Two outpatient visits are planned according to the standard follow-up of the treatment of a chronic subdural hematoma at the HUG: a first visit at 6 weeks after treatment and a second at 6 months after treatment. During these visits, a brain scan and a clinical follow-up consultation will be carried out.

The appointments are detailed in **the table in Chapter 5**.

You will learn more about the process and procedures of the study in **Chapter 5**.

3. What are the benefits and risks of participation?

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Benefits

There is no guarantee of direct benefit to you by participating in this study.

Possible benefits are a reduction in the medium to long-term recurrence of your subdural bleeding.

However, your participation can help future patients.

Risks

The method of middle meningeal artery embolization for the standard treatment of subdural hematomas is new and has not yet been tested in this pathology.

Although no major complications have yet been described as directly related to middle meningeal artery embolization in the literature, side effects may occur if you are treated with this method of intervention. We may not yet know all the risks and side effects of this method of intervention. So far, the following risks and side effects are known:

- Artery dissection
- Neurological deficits resulting from stroke or arterial injury
- Allergic reaction to the contrast medium.

More information on risks and constraints can be found in **Chapter 6**.

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Part 2: Detailed information about the study

4. Scientific background

4.1 Background: Why are we conducting this study?

In the presence of symptomatic subdural hematomas (accumulation of blood), surgical evacuation of the hematoma is performed in order to avoid serious sequelae and to allow maximum neurological recovery. However, a recurrence of these hematomas is often observed. This recurrence is a complication that we want to avoid at all costs because it exposes the patient to new neurological sequelae, and to the risks of a new surgery. The studies conducted so far suggest that embolization (obstruction) of the middle meningeal artery (the artery that promotes this bleeding) in addition to surgical evacuation of the hematoma would limit the recurrence of the hematoma. In this study, we therefore examine the effectiveness of embolization of the middle meningeal artery in the recurrence of subdural hematomas. This technique has not yet been validated in Switzerland for the standard treatment of subdural hematomas. The available results are based only on preliminary studies. Only when the effectiveness of this method of intervention has been scientifically studied and proven can it be approved in Switzerland for the treatment of subdural hematomas.

In addition, we are investigating whether this new treatment could be beneficial for patients in whom surgical treatment is contraindicated.

4.2 Study structure: how do we do it?

Patients who meet the inclusion criteria of the study, and who consent to it, will be randomly assigned to groups, this is called randomization. This method is important for reliable results. Each group receives a different treatment. In our study, there are 4 groups:

- **Group 1** (control group) is treated according to conventional management, i.e. the hematoma is surgically removed without embolization of the middle meningeal artery.
- **Group 2** (intervention group) is treated surgically and by embolization of the middle meningeal artery within 72 hours after surgical evacuation of the subdural hematoma.
- **Group 3** corresponds to patients in whom surgical treatment is contraindicated but who accept embolization of the middle meningeal artery.
- **Group 4** corresponds to patients in whom surgical treatment is contraindicated and who refuse embolization of the middle meningeal artery.

Follow-up will be carried out according to the standard clinical protocol of the department: two follow-up visits will be organized for all participants: one visit at 6 weeks and another at 6

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183 months after treatment. At each visit, a brain scan and a clinical consultation will be carried
184 out.

185 4.3 Regulation of scientific research involving human subjects

186 We carry out this study in accordance with the laws in force in Switzerland (Human Research
187 Act, data protection laws). In addition, we comply with all internationally recognized
188 guidelines. The relevant ethics committee has reviewed and approved the study.

189 Our study is a national study. There are 2 participants in Switzerland.

190 A description of this study can also be found on the website of the Federal Office of Public
191 Health at www.kofam.ch under the registration number SNCTP ..... or BASEC number .....

192 5. Conduct of the study

193 5.1 What should you do if you participate in the study?

194 Participation in the study is voluntary and lasts for 6 months. You must respect the
195 appointment schedule (→ chapter 5.2) as well as all the instructions given by the research
196 team.

197 You must inform the research team

198 • if your health changes, for example if you feel worse or if you have new conditions; you
199 should continue to inform them if you withdraw from the study (→ Chapters 5.3 and 5.4).
200 • any treatment or therapy prescribed by another doctor and any medications you are
201 taking;
202 • If you discover that you are pregnant during the study, you must inform the investigating
203 physician immediately and you will be excluded from the study. In this case, you will be
204 asked to provide information about the course and outcome of the pregnancy. The
205 investigating physician will discuss with you what to do (→ chapter 5.5).

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5.2 What happens during the appointments?

You will come to the study center 2 times. Both of these appointments are part of your standard treatment and are performed regardless of your participation in the study. A date lasts about 30 minutes. The list of appointments is shown in the table below.

Here's what we do at all appointments:

- We answer your questions.
- We ask you questions about your state of health.
- We will perform a brain scan.

These examinations allow us to assess the effectiveness and safety of the intervention method.

Please note that it is not possible to postpone an appointment. If you still have to reschedule an appointment for important reasons, we ask you to inform us as soon as possible.

5.3 When does participation in the study end?

Your participation lasts for 6 months after the treatment. You may discontinue your participation at any time before this date (→ Chapter 5.4). You don't need to justify yourself. If you wish to terminate your participation, please inform the investigating physician.

If you withdraw from the study, your treatment and medical care will be provided according to current standards (→Chapter 5.4 for other treatment options). In this case, we will carry out a final examination, as part of the study, for your safety.

If you stop your stay before the scheduled date, we ask you to continue to inform the investigator if your health changes, for example if you feel worse or if new disorders appear. If you withdraw from the study, we will still be able to analyse the data collected so far (e.g. brain scan results).

We may also have to exclude you from the study early. This situation can occur, for example, if you decide to move abroad. In this case, we will offer to examine you one last time for your own safety.

5.4 What happens if you don't want to participate?

If you do not participate in this study, your treatment and medical care will be provided according to current standards. If you do not wish to take part in the study, the investigating physician will present you with alternatives/alternative treatment options in an interview.

5.5 Pregnancy

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The procedure is not yet authorized, it could be dangerous and harmful to an unborn child. For women of childbearing potential, a pregnancy test will be performed prior to the start of the study. Pregnant women will be excluded from the study.

If you discover that you are pregnant during the study, you must inform the investigating physician immediately and you will be excluded from the study. In this case, you will be asked to provide information about the course and outcome of the pregnancy. The medical investigator will discuss with you what to do.

6. Risks, constraints and side effects

6.1 What are the risks and constraints associated with the study?

Participation in this study involves risks and constraints, like any medical treatment. We already know some risks, others are still unknown. This uncertainty is not unusual in a study setting. A list of the most common and serious risks can be found in **Chapter 6.2**. Many side effects can be treated medically. We will inform you during the study of any new knowledge about the risks and side effects.

A new method of intervention can lead to risks that we do not yet know. We still know little about this embolization technique, but this technique seems to involve less risk than surgery, due to the possibility of performing it without general anesthesia and the absence of risks directly related to surgery.

The medical examinations we carry out as part of the study also carry risks. Some examinations are already part of your standard care and your doctor has explained the risks to you. A **list of risks associated with examinations** can be found in Chapter 6.3.

6.2 Most frequent and severe risks associated with the intervention method

Here you can find information about the most common and serious side effects that we already know.

We use the following categories to describe them:

Very common	The side effect occurs in more than 10 out of 100 people (more than 10%).
Frequent	The side effect occurs in 1 to 10 in 100 people (1%-10%).
Occasional	The side effect appears in 1 to 10 out of 1000 people (0.1%-1%).
Rare	The side effect occurs in 1 to 10 in 10,000 people (0.01%-0.1%).
Very rare	The side effect occurs in less than one in 10,000 people (less than 0.01%).

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Common side effects are:

- Headache
- Pain at the site of the arterial puncture to perform the interventional procedure

Occasional side effects are:

- Vascular accident due to vascular injury or embolization equipment
- Arterial thrombosis or dissection at the arterial puncture (most often the femoral artery)

6.3 Risks and Constraints of Study Reviews

We perform various medical examinations for this study (→Chapter 5.2). These examinations are proven procedures. Nevertheless, they can carry risks and constraints, i.e. they can be unpleasant or have undesirable side effects. In this study, the risks and constraints are as follows: The proposed brain scans will be performed without injection of contrast medium. However, they expose participants to X-ray irradiation, i.e. 2 mSv at each examination, about the equivalent of 100 long-haul flights. These scans are part of the standard protocol for monitoring patients with a subdural hematoma.

7. Funding and Compensation

This study is initiated and financed by the sponsor: Geneva University Hospitals. This study is also funded by the HUG private foundation and will be partially funded by other sources in the future.

The researchers involved in the study do not derive any direct financial benefit from this.

If you participate in this study, you will not receive any money or any other compensation.

There are no additional costs to you or your health insurance to participate in the study.

The results of this study can contribute to the commercialization of a drug. Your participation does not give you any rights regarding its commercial exploitation.

8. Study results

The results that concern you personally are communicated to you by the investigating physician. Sometimes results are discovered by chance. For example, these can be results from the brain scan. We inform you if these findings are important for your health.

For example, we will inform you if we discover a disease that you are not yet aware of and that we can treat. We also inform you if we find a risk of disease that can be avoided by preventive measures. If you *do not wish to* receive this information, please speak to the investigating physician.

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In addition to individual results, the study will produce overall results that come from the data of all participants. This would include, for example, new knowledge on the effectiveness of the treatment of subdural hematomas (→ Chapter 4.1). These results do not directly concern you or your health. If desired, the investigating physician will provide you with a summary of the overall results at the end of the study.

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Part 3 : Data Protection and Insurance Coverage

9. Data and sample protection

We protect your data from your medical records and examinations. Swiss laws provide for strict rules on data and sample protection.

9.1 Data and sample coding

Every study generates data from examinations (e.g. brain scan). This data is recorded in an encrypted manner, usually in electronic form. Encryption means that personal information is kept *separate* from other data, in the form of a list that identifies each person with a unique code. This means that your name, date of birth or address *do not appear* directly with the other data collected. This list remains in the hospital for 10 years . No one else receives it.

At the end of the study, your data will be irreversibly anonymised, but at the earliest at the end of the legally prescribed storage period. This means that it will no longer be possible to re-identify yourself without disproportionate effort. This involves several de-identification measures, including the destruction of the code and the list.

When we transmit data – to the developer or to specialists who carry out further analyses – it is always encrypted and your personal data is protected. The same applies when the data is transferred abroad.

9.2 Data and sample security during the study

The sponsor "Hôpitaux Universitaires de Genève" is responsible for the security of your data and the samples of this study. It ensures compliance with applicable laws, such as data protection laws. This rule also applies when data or (coded) samples are sent for analysis to countries with less stringent data protection laws. Here's how the study sponsor protects your data:

- As part of this study, data about your person and your health is collected and processed in part by automation. This information is coded at the time of the survey. Coding means that all the data that identifies you (name, date of birth, etc.) is replaced by a code. It is not possible to link the data to you without the code that remains permanently within the HUG.
- Only a limited number of people can view your data in an unencrypted form, and this is exclusively for the purpose of performing tasks necessary for the conduct of the study. These persons are bound by professional secrecy. As a participant, you have the right to view your data.

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- All data protection guidelines are strictly adhered to. It is possible that your data will need to be transmitted in encrypted form, for example for a publication, and that it may be made available to other researchers. The sponsor must ensure that the destination country guarantees data protection equivalent to that guaranteed in Switzerland.
- In this study, your data is collected and transmitted electronically. The data is stored on a server in Switzerland. Nevertheless, the risk of unauthorised persons gaining access to your personal data cannot be completely excluded (e.g. the risk of "hacking").

It may be important for your primary care physician to share data from your medical record with the research team. This also applies to other doctors who follow you. By signing the consent at the end of the document, you authorize the release of this data.

9.3 Data and Sample Security at the End of the Study

Once the study is complete, the sponsor continues to ensure the security of your data and samples. The law requires that all study documents, such as data collection forms, must be kept for at least 10 years.

Once the study is complete, the results are usually published in scientific journals. To do this, the data is sent in coded form to other specialists so that they can review the publication. This data cannot be reused for research purposes. Such re-use for other research purposes requires your separate consent (see Chapter 9.4).

9.4 Reuse of your data and samples for other studies

The data from this study are very important for future research. Data that have not been fully used may be used for future studies. Separate consent for the reuse of your data is required. This is optional. We invite you to read carefully the additional declaration of consent at the end of the document. Please sign the consent if you agree to make your data available for future research. You can participate in the study even if you do not sign this additional document.

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9.5 Right of consultation during inspections

The performance of this study may be subject to controls. These checks are carried out by authorities such as the competent ethics committee or the Swissmedic authorisation authority, or by foreign authorisation authorities. The sponsor must also carry out checks to ensure the quality of the study and its results.

For these checks, a small number of specially trained people have access to your personal data and medical records. In this context, the data are therefore not encoded. Persons who consult your non-encrypted data are subject to professional secrecy.

10. Insurance coverage

You will receive insurance cover if you suffer damage as a result of the study – i.e. due to the method of intervention of embolisation of the middle meningeal artery. The procedure is regulated by law. The developer has taken out insurance with the company Baloise. If you believe that you have suffered damage as a result of the study, please contact the investigating physician or the insurance company directly.

If damage results from the proper use of the application of conventional treatment, the rules on liability are the same as for treatments outside of a study. In such cases, the hospital's liability insurance covers the costs/compensation.

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Part 4: Declaration of Consent

This declaration of consent consists of two separate parts:

- Statement of Consent for Participation in the Study: Middle Meningeal Artery Embolization for Chronic Subdural Hematomas: A Randomized Clinical Trial to Determine the Likelihood of Recurrence After Embolization
- Declaration of consent for the reuse of the data from this study in encrypted form

Please read this form carefully. Please feel free to ask us any questions if you do not understand something or if you would like clarification. Your written consent is required to participate.

Declaration of consent for participation in the study

BASEC Number	2023-xxxx
Study title	Middle Meningeal Artery Embolization for Chronic Subdural Hematomas: A Randomized Clinical Trial to Determine the Likelihood of Recurrence After Embolization
Simplified title	STORMM
Responsible institution (sponsor and address)	Pr. Karl Schaller Neurosurgery Department Department of Clinical Neurosciences HUG Rue Gabriel-Perret-Gentil, 4 1211 Geneva 14 Phone: +41 (0)22 372 82 02 email : Karl.Schaller@hcuge.ch
Place of realization	Department of Neurosurgery, HUG
Physician-investigator in charge on site	Dr. Aria Nouri Neurosurgery Department, Department of Clinical Neurosciences HUG Rue Gabriel-Perret-Gentil, 4

	Phone: +41 (0)795530958 Email: Aria.Nouri@hcuge.ch
Participant Full name in print: Date of birth:	

- In my capacity as a relative or legal representative of the above-mentioned patient, I have received written and oral information from the undersigned physician investigator about the objectives and progress of the research project as well as the possible advantages, disadvantages and risks.
- I confirm that I am making the decision in the direction of the relative or person under my responsibility, i.e. that he/she participates in the research project. On his behalf, I accept written and oral information. I had enough time to make my decision.
- I have received the answers to the questions I asked in relation to participating in this project. I keep the information sheet and receive a copy of my declaration of consent.
- In the event of further treatment outside the location of this project, I authorize the patient's physicians to provide the investigating physician with the study-relevant post-treatment data.
- I was informed of the therapeutic alternatives to the project, e.g. the existence of other treatments and therapies.
- I agree that the patient's treating physician will be informed of his/her participation in the research project.
- In the event of further treatment outside the place where this study is conducted, I authorize the physician(s) to provide the investigating physician with the patient's post-treatment data relevant to the study.
- I agree that the competent specialists of the project sponsor, the competent ethics committee and the Swiss Therapeutic Products Supervisory Authority Swissmedic may consult the patient's unencrypted data for the purpose of carrying out checks and inspections, provided that the confidentiality of this data is strictly ensured.
- I will be informed instead of the patient about the results that have a direct impact on their health. If I feel that this is not the project participant's wishes, I will notify the project physician.
- I know that personal data and health data can be passed on for research purposes within the scope of this study and only in coded form, also abroad. The promoter ensures data protection in accordance with Swiss standards and requirements.
- On behalf of the patient, I can revoke their consent to participate in the study at any time and without having to give reasons, without this decision having an adverse impact on the patient's further care. However, the data that has been collected so far will be analysed as part of the study.
- I am informed that insurance has been taken out by the University Hospitals of Geneva to cover the damage attributable to the project that the patient may suffer.
- I am aware that the obligations mentioned in the participant information sheet must be respected throughout the duration of the study. The investigating physician may exclude the patient from the study at any time in the interest of his or her health.

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Attestation from the relative or legal representative: I hereby certify that the informative interview has taken place and the adult incapable of discernment has consented to participate in this study and/or that there are no signs of opposition to his/her participation.

Location, date	First and last name in print Relationship with the patient: ☐ Person named in advance directives or in a power of attorney ☐ Curator ☐ Spouse or partner registered and providing regular personal assistance ☐ Person living in common with the participant and providing regular personal assistance ☐ Descending and providing regular personal assistance ☐ Father/Mother and providing regular personal assistance ☐ Brother/Sister and providing regular personal assistance Signature of the relative or legal representative:

Attestation from the Physician Investigator: I hereby certify that I have explained to the participant's relative or legal representative the nature, importance and scope of the project. I declare that I meet all obligations in connection with this project in accordance with the applicable law. If, at any time during the project, I become aware of any elements that may affect the participant's consent to take part in the project, I undertake to inform his/her loved one or legal representative immediately.

Location, date	Name and first name of the investigating physician in block letters. Signature of the investigating physician:

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448 **Declaration of consent for the reuse of data in encrypted form**

449 This consent does not cover the patient's individual participation in a study. "Reuse" means
450 that data can be retained beyond participation in the study and used in coded form for other
451 studies. For example, patient data can be analysed together with a large amount of other
452 data, or new analyses can be carried out with this data.

453

BASEC number of the study (after submission to the competent ethics commission):	2023-XXXX
Title (scientific and usual):	**Middle Meningeal Artery Embolization for Chronic Subdural Hematomas: A Randomized Clinical Trial to Determine the Likelihood of Recurrence After Embolization** **Middle Meningeal Artery (MMA) Embolization for cSDH: Rationale and Design for the STOp Recurrence of MMA Bleeding (STORMM) Randomized-Control Trial**
Participant: First and last name in print: Birth date:	

454

455 • I authorize the reuse of the patient's data from this study in coded form for medical
456 research purposes. They will be available for future research projects, for an indefinite
457 period of time.
458 •
459 • I understood that the data is encrypted and that the identification list is kept securely.
460 •
461 • The data can be analysed in Switzerland and abroad and stored in a database in
462 Switzerland or abroad. Research institutions abroad must comply with the same data
463 protection standards as those in Switzerland.
464 •
465 • I make my decision of my own free will and I can reconsider my decision at any time. If I
466 withdraw my consent, all patient data will be anonymised. I simply inform the
467 investigating physician of my decision. I don't have to justify myself.

-
- In principle, the data is analysed holistically. If by chance a result that is very important for the patient's health comes to light, the person responsible will contact me. If I don't want to, I talk to the investigator.

Attestation from the relative or legal representative: I hereby certify that the informative interview has taken place and the adult incapable of discernment has consented to participate in this study and/or that there are no signs of opposition to his/her participation.

Location, date	First and last name in print Relationship with the patient: ☐ Person named in advance directives or in a power of attorney ☐ Curator ☐ Spouse or partner registered and providing regular personal assistance ☐ Person living in common with the participant and providing regular personal assistance ☐ Descending and providing regular personal assistance ☐ Father/Mother and providing regular personal assistance ☐ Brother/Sister and providing regular personal assistance Signature of the relative or legal representative:

Attestation from the Physician Investigator: I hereby certify that I have explained to the participant's relative or legal representative the nature, importance and scope of the project. I declare that I meet all obligations in connection with this project in accordance with the applicable law. If, at any time during the project, I become aware of any elements that may affect the participant's consent to take part in the project, I undertake to inform his/her loved one or legal representative immediately.

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Location, date	Name and first name of the investigating physician in block letters. Signature of the investigating physician:

Written confirmation from a physician not associated with the research project

Written confirmation for the doctor who is not involved in the research project, who is *not* involved in the research project mentioned below and who defends the interests of the person taking part in the experiment (LRH art 30).

Clinical Trial Data

Research Project Title: **Middle Meningeal Artery Embolization in Chronic Subdural Hematomas: A Randomized Clinical Trial to Determine the Likelihood of Recurrence After Embolization**	
Research project number: 2023-XXXX	
Location of the research project: Geneva University Hospitals	
Name and surname of the investigator in charge: Prof Karl Schaller	
Name and surname of the participant:	
Date of birth (optional):	Gender (optional):

I have received and read the protocol summary for the above-mentioned clinical trial.

I certify that the interests of the participant are respected and that his or her medical follow-up is guaranteed.

Location, date	Last name, first name and telephone number of the physician not associated with the research project (in print)	Signature of the physician not associated with the research project

I hereby certify that I have explained to the physician not associated with the research project the nature, importance and scope of the project. If I become aware, at any time during the project, of any elements that may influence the participant's consent to take part in the research project, I undertake to inform him/her immediately.

Location, date	Surname, first name and telephone number of the investigator in charge (in print)	Signature of the Investigator in Charge

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Al Awadhi A, *et al. BMJ Open* 2025; 15:e092014. doi: 10.1136/bmjopen-2024-092014