Patient information[1] and declaration of consent for participation in the clinical trial

Obsidian® - ASG Autologous platelet-rich fibrin matrix for the prevention of postoperative pancreatic fistula after pancreatic resection - A feasibility study

Dear Patient!

We invite you to take part in the above-mentioned clinical trial. You will be informed about this in a detailed medical consultation.

Your participation in this clinical trial is voluntary. You can withdraw from the trial at any time without giving reasons. Refusal to participate or early withdrawal from this trial will have no adverse consequences for your medical care.

Clinical trials are necessary in order to obtain reliable new medical research results. However, an essential prerequisite for conducting a clinical trial is that you give your written consent to participate in this clinical trial. Please read the following text carefully as a supplement to the information meeting with your investigator and do not hesitate to ask questions.

Please sign the declaration of consent only

- if you have fully understood the nature and procedure of the clinical trial,
- if you are willing to agree to participate and
- if you are aware of your rights as a participant in this clinical trial.

The responsible ethics committee issued a favourable opinion on this clinical trial, as well as on the patient information and consent form.

1. What is the purpose of the clinical trial?

The purpose of this clinical trial is to test the feasibility of a new method to avoid complications after your operation. You are admitted to the Department of General Surgery (Division of Visceral Surgery) of the Medical University of Vienna due to a disease of the pancreas, which is to be treated by surgery in the near future at the Department of General Surgery (Division of Visceral Surgery) of the Medical University of Vienna. The aim of this operation is to remove the diseased part of your pancreas. As part of this operation, the pancreas must be cut approximately in the centre. The aim is to preserve part of the gland. In the course of the operation on the

[1] For the sake of readability, the use of the masculine and feminine forms in the following text is omitted in some cases. The use of personal terms is avoided. Where applicable, both genders are always meant and addressed.

The pancreas often leaks at the point where the pancreas is severed, causing pancreatic juice to leak into the abdominal cavity. This is called a "pancreatic fistula". This is also the most common complication of the operation and requires this fluid to be drained to the outside - usually for a longer period of time (possibly several weeks). This often requires the insertion of an additional drainage tube from the outside as part of an X-ray examination (computerised tomography). In rare cases, more serious problems (bleeding, infections) can also be caused by the pancreatic fistula. An important goal is therefore to prevent the occurrence of such a pancreatic fistula, but despite the greatest care, surgical measures during the operation do not succeed in every fourth patient.

We would therefore like to invite you to take part in a study in which we would like to try to prevent the occurrence of a pancreatic fistula in a completely new way. It is possible to produce a fluid from the body's own blood, which is applied to the incision site of the pancreas during the operation and is intended to support the healing and sealing of the incision site. This fluid has already been used successfully in intestinal surgery. To date, there have been no studies on its use in pancreatic surgery. We assume that the described measure can significantly reduce the frequency and severity of pancreatic fistula and would first like to investigate the feasibility of administration in a clinical trial.

2. What other treatment options are there?

The following options are **also** available to treat your condition **instead**: if you do not wish to take part in the study, the operation will take place without using the additional method.

3. How does the clinical trial work?

This clinical trial will be conducted at the Department of Visceral Surgery and will involve a total of approximately 25 participants.

Before being admitted to this clinical trial, your medical history will be taken and you will undergo a comprehensive medical examination.

Your participation in this clinical trial is expected to last 12 weeks.

A number of examinations and procedures will be carried out as part of your treatment, regardless of whether you are taking part in this clinical trial or not. These will be discussed with you by your investigator as part of the usual medical consultation.

The following measures are carried out exclusively for study reasons:

During this clinical trial, 120ml of blood will be taken from you on the day of the operation (equivalent to about 8 tablespoons). This blood will then be used to prepare the fluid that will be used during your operation to seal the incision in the pancreas. You will be visited regularly by study doctors after the operation so that we can monitor your progress. After you are discharged home, we will visit you again on the 30th and 90th day after the operation or contact you by telephone. A total of 7 study visits are planned, with the first 5 taking place while you are in hospital anyway. Further measures are not specific to the study, but would also be carried out without participation in the operation.

4. What is "Obsidian® - ASG Autologous Platelet Rich Fibrin Matrix"?

Obsidian®-ASG Autologous Platelet Rich Fibrin Matrix is a medical device that is already authorised for use in surgery. This medical device is currently used in particular for the treatment of intestinal diseases. It has been used in over 200 patients to date.

5. What are the benefits of participating in the clinical trial?

The use of Obsidian®-ASG Autologous Platelet Rich Fibrin Matrix may improve the outcome of your surgery by preventing complications altogether or at least significantly reducing their severity. However, it is also possible that your participation in this clinical trial will not directly benefit your health. However, it is possible that you will gain scientific knowledge and benefit the future treatment of patients.

6. Are there risks, complaints and side effects?

Treatment with Obsidian®-ASG Autologous Platelet Rich Fibrin Matrix may cause side effects or discomfort. The side effects and discomfort observed to date include after-effects of blood collection such as pain at the puncture site or bruising. This occurs frequently (in more than half of patients), but usually heals quickly and without consequences. Very rarely (in 5 out of 100 patients), a small nerve can also be injured when blood is drawn. Very rarely (in 5 out of 100 patients) allergic reactions to the ingredients of the product may occur. If you have a known allergy, you must not take part in the study. As with any new substance, the use of Obsidian®-ASG Autologous Platelet Rich Fibrin Matrix may cause new, previously unknown side effects.

7. Taking additional medication?

You do not need to change your medication as a result of participating in the study.

8. Does participation in the clinical trial have any other effects on your lifestyle and what obligations does this entail?

No.

9. What should I do if symptoms, side effects and/or injuries occur?

If any symptoms, side effects or injuries occur during the course of the clinical trial, you must report them to your investigator, in the case of serious side effects immediately, if necessary by telephone (see below for telephone numbers, etc.).

10. Insurance

As a participant in this clinical trial, you have the statutory no-fault insurance cover (personal injury insurance in accordance with Section 20 of the Medical Devices Act, which covers all damage that may be caused to your life or health by the clinical trial measures carried out on you, with the exception of damage due to changes in the genetic material in germline cells.

The insurance was taken out for you with Zurich Insurance Company as part of a framework insurance policy of the Medical University of Vienna for clinical studies (policy no. 07229622-2).

You can inspect the insurance documents on request.

In the event of a claim, you can contact the insurer directly and assert your claims independently. The insurance contract is governed by Austrian law and insurance claims are enforceable in Austria.

For support, you can also contact the patient advocacy organisation, patient representative body or patient ombudsman.

In order not to jeopardise the insurance cover

- you may only undergo other medical treatment for the duration of the clinical trial with the agreement of your treating investigator **(with the exception of emergencies).** This also applies to the additional intake of medication or participation in another study.
- you must immediately notify the treating investigator - or the insurance company mentioned above - of any damage to your health that may have occurred as a result of the clinical trial.
- you must do everything reasonable to clarify the cause, course and consequences of the insured event and minimise the damage incurred. This may also include authorising your attending physicians to provide information requested by the insurer.

11. Information for women of childbearing age - Pregnancy test

Pregnant and breastfeeding women are NOT allowed to participate in this clinical trial.

As a woman of childbearing potential, you may only participate in the clinical trial,

- if a doctor determines the absence of pregnancy (pregnancy test) before the clinical trial.
- if you undertake to use a reliable form of contraception (pill, coil) for the duration of the treatment.

Should you nevertheless become pregnant during the clinical trial or suspect that you have become pregnant, please inform your investigator immediately. The gynaecology department will then be contacted immediately.

12. When is the clinical trial terminated prematurely?

You can withdraw your willingness to participate at any time without giving reasons and withdraw from the clinical trial without any disadvantages for your further medical care.

Your investigator will inform you immediately of any new findings that become known in relation to this clinical trial that could be significant for you. On this basis, you can then reconsider your decision to **continue** participating in this clinical trial.

However, it is also possible that your investigator (or, if applicable, the sponsor of this clinical trial) may decide to terminate your participation in the clinical trial prematurely without first obtaining your consent. The reasons for this may be

a) They cannot fulfil the requirements of the clinical trial;

b) Your investigator has the impression that further participation in the clinical trial is not in your interest;

c) the sponsor makes the decision to cancel the entire clinical trial or only to terminate your participation prematurely.

If you decide to withdraw from the clinical trial prematurely, or if your participation is terminated prematurely for one of the reasons mentioned above, it is important for your own safety that you undergo a normal check-up. This usually consists of a physical examination and laboratory tests.

13. Data protection

Data about you will be collected and processed as part of this clinical trial. A basic distinction must be made between

1) personal data by which a person can be directly identified (e.g. name, date of birth, address, national insurance number, photographs, etc.),
2) pseudonymised personal data, i.e. data in which all information that allows direct conclusions to be drawn about the specific person is either removed, replaced by a code (e.g. a number) or (e.g. in the case of image recordings) made unrecognisable. However, despite compliance with these measures, the possibility of unauthorised re-identification cannot be completely ruled out.
3) anonymised data that cannot be traced back to a specific person.

The investigator and other employees of the trial centre who are involved in the clinical trial or your medical care have access to the data by which you can be directly identified (see point 1). In addition, authorised representatives of the sponsor, the Medical University of Vienna, as well as representatives of domestic and/or foreign health authorities and the relevant ethics committees, who are bound to confidentiality, may inspect this data insofar as this is necessary to verify the proper conduct of the clinical trial. All persons who have access to this data are subject to the applicable national data protection regulations and/or the EU General Data Protection Regulation (GDPR) when handling the data.

The code that makes it possible to assign the pseudonymised data to your person is only stored at your test centre.

The data will only be passed on in pseudonymised or anonymised form.

Only pseudonymised or anonymised data will be used for any publications.

No transfer of data to countries outside the EU (third country) is planned as part of this clinical trial.

Your consent forms the legal basis for the processing of your personal data. You can withdraw your consent to the collection and processing of your data at any time without giving reasons. After your revocation

no further data will be collected about you. However, the data collected up to the point of cancellation may continue to be processed in the context of this clinical trial.

According to the GDPR, you are generally entitled to the rights of access, rectification, erasure, restriction of processing, data portability and objection, provided that this does not render impossible or seriously impair the objectives of the clinical trial and provided that this does not conflict with other statutory provisions.

You do not have the right to erasure of your data processed in the context of this clinical trial as provided for in the GDPR due to regulations under the German Drug Law and Medical Devices Law. In addition, the right to data portability is overridden in the case of a clinical trial under the Medicinal Products Act.

The expected duration of the clinical trial is 12 months. The duration of the storage of your data beyond the end or cancellation of the clinical trial is regulated by legal provisions.

If you have any questions about the handling of your data in this clinical trial, please contact your investigator first. If necessary, they can forward your request to the persons responsible for data protection.

Contact details of the data protection officers of the institutions involved in this clinical trial: Data

Protection Officer of the MedUni Vienna: datenschutz@meduniwien.ac.at Data Protection Officer of the

AKH: datenschutz@akhwien.at

You have the right to lodge a complaint with the Austrian data protection authority about the handling of your data (www.dsb.gv.at; e-mail: dsb@dsb.gv.at).

14. Are there any costs for the participants? Is there a reimbursement of costs or remuneration?

Your participation in this clinical trial will not incur any additional costs for you, with the exception of the travelling costs for the follow-up 30 days after the operation. However, a check-up is also recommended at this time regardless of participation in the trial. No compensation is provided.

15. Possibility to discuss further questions

Your investigator and his staff will be happy to answer any further questions you may have in connection with this clinical trial. They will also be happy to answer any questions concerning your rights as a patient and participant in this clinical trial.

I. Name of contact person: Priv.-Doz. Dr Ulla Klaiber

Always available at : Mobile: +43 67764384772

II. Name of contact person: Dr Charlotte Gustorff

Always available under: Mobile: +43 6703501743

19. declaration of consent

Name of the patient:

Date of birth:

I agree to participate in the Obsidian clinical trial for the reduction of pancreatic fistula. I have been informed that I can refuse to participate without adverse consequences, in particular for my medical care.

I was informed by Mrs/Mr (Dr.med.) .....in detail and comprehensibly about the I have been informed about the nature, significance and scope of the clinical trial, the existing insurance and the resulting requirements for me. I have also read the text of this patient information and consent form, which comprises a total of 7 pages. Any questions that arose were answered clearly and satisfactorily by the investigator. I had sufficient time to make a decision. I currently have no further questions.

I will follow the medical instructions necessary for the conduct of the clinical trial, but I reserve the right to terminate my voluntary co-operation at any time without any disadvantages, in particular for my medical care.

I expressly consent to the processing of my data collected in the course of this clinical trial as described in the "Data Protection" section of this document.

I have received a copy of this patient information and consent form. The original remains with the investigator.

.....
(Date and signature of the patient)

.....
(Date, name and signature of the responsible investigator)

(The patient receives a signed copy of the patient information and consent form, the original remains in the investigator's study folder).