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Patient Information

ViP-Trial

Intraoperative Pancreatic Leakage Indicator – Post Market Confirmatory Study (PMCF, IDEAL Stage I)

Dear Patient,

we invite you to participate in a clinical study. Please take a moment to learn about the ViP trial being conducted at our hospital. This is intended to confirm the safety and effectiveness of SmartPAN®, an indicator for the intra-operative visualization of pancreatic leaks. The verbal information about the study will take about 20 minutes.

Please read this information carefully so that you can decide whether or not to participate in the trial. Your study doctor will discuss the details of the trial with you and answer your questions. You will then be given sufficient time to decide whether to participate. If you would like to participate in the trial, we ask that you sign the attached consent form, confirming that you fully understand the information provided and that you agree to participate in this trial. The trial presented here was developed by the Department of General, Visceral and Transplantation Surgery at Heidelberg University Hospital and is also being carried out here. The overall head of the trial is Prof. Dr. medical Thilo Hackert. In accordance with medical professional law, advice was given by the ethics committee of the medical faculty of the University of Heidelberg. In total, it is planned to include 35 patients at our hospital in this trial.

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Why is this trial being conducted (background and purpose)?

You have been diagnosed with a disease of the pancreas and the treatment planned is surgical removal (resection) of the altered tissue. The doctor treating you will provide you with detailed information about the planned operation.
The most critical complication after an operation on the pancreas is the postoperative pancreatic fistula. Postoperative pancreatic fistula occurs when pancreatic fluid leaks from the remnant of the pancreas, which can result in inflammation, bleeding, and prolonged hospitalization. However, the pancreatic fluid is not visible to the naked eye during the operation. A color indicator is used to make leaks visible during the operation. As a result, the closure suture on the pancreas stump can be checked and, if necessary, corrected during the operation.
The aim of this trial is to continuously confirm the existing data on the usability, reliability and security of SmartPAN® with further information, as required by law.

What if I don't want to take part in the trial (voluntarily)?

Your participation in this trial is voluntary. You will only be included in this study if you have given your written consent. If you do not want to take part in the trial, you will of course not suffer any disadvantages in terms of further treatment. The current standard therapy at our clinic does not provide for the use of SmartPAN® or any other indicator during the operation. The surgeon will inform you about this and discuss the treatment with you.

Which methods are used and examined as part of the trial?

The SmartPAN® indicator is a medical product that was developed in cooperation with the Swedish company Magle Chemoswed and is approved for use in humans. It contains biodegradable starch beads, phosphate buffers and bromothymol blue, which are also routinely used in humans..

What are the benefits and risks of participating in the trial?

All patients are operated according to the latest surgical knowledge. A possible advantage is that the surgeon can already react to the leakage of pancreatic fluid during the operation and thus has the chance to reduce the risk of the occurrence and the complications of a pancreatic fistula. This would make the operation safer overall for the patient. Extensive safety data are available for the components of SmartPAN®, as they are known from other routine applications. They are compatible with the human body (biocompatible) or are quickly neutralized by dilution and drainage.

However, there is a very small potential risk of an allergic reaction to any component of SmartPAN®. It is no greater than the risk of an allergic reaction to other biomaterials routinely used in medicine.

The use of SmartPAN® in this study corresponds exclusively to the area of application according to the approval.

In addition to the scheduled routine blood sampling during the operation, 8ml of blood will be drawn from the central venous catheter for study purposes. However, this only poses a minimal risk.

Intervention in trial participants

Pancreas surgery is performed according to clinical standards. Once the remnant of the pancreas has been occluded, the SmartPAN® Pancreatic Leakage Indicator is applied using a standardized procedure in accordance with the product's Instructions for Use (IFU). The surgical site is then irrigated and the fluid is aspirated and, if necessary, drained to avoid accumulation of the product in the abdominal cavity. If a pancreatic leak becomes visible after application of the indicator, the surgeon can place additional sutures to close the leak and reapply SmartPAN® to confirm the seal. Fifteen minutes after the application, an 8ml blood sample is taken for study purposes and a sample of the fluid is taken from the abdominal cavity at the end of the procedure. If the surgeon places drains to drain fluid from the abdominal cavity, the drain fluid is examined for pancreatic enzymes and bromothymol blue on the second day after the operation. On that day, another 8ml of blood will be taken for study purposes. A total of 16ml of blood is taken.

What alternative therapy options are there?

The alternative therapy option is the current standard of care. The current standard of care does not include the use of an indicator to detect pancreatic leakage after pancreatic resection.

How is the trial going on?

Trial visits: A few days before the operation, after your written consent to participate in the trial, the inclusion and exclusion criteria will be checked and data on your age, height and weight as well as your medical history will be collected. This survey will take approximately 10 minutes. At the beginning of the trial and 30 days after the operation, you will be asked to answer a questionnaire with questions about your condition. Each will take about 10 minutes.

During the 30-day follow-up observation, all data relevant to answering the question about the course of your recovery and any complications that may arise are documented. Employees of the study team will visit you during your inpatient stay on the 2nd, 7th and 30th postoperative day after the operation (and, if necessary, on the day of discharge) or contact you by phone to personally check on your condition and the postoperative course to ask. The rounds and phone calls will last a maximum of 10 minutes. In order to carry out the study successfully, we depend on your active cooperation and therefore ask you to regularly take part in the follow-up visits.

This not only serves to record the trial data more precisely, but also allows precise aftercare and optimal care for you. Please inform your supervising study staff about any complications during the course.

How is further treatment carried out?

The further treatment after the operation (also after the end of your participation in the trial) takes place according to the specifications of your doctor and the therapy standards.

Who organizes and finances the trial?

The ViP trial is being conducted by the Department of General, Visceral and Transplantation Surgery at Heidelberg University Hospital. Magle Chemoswed AB, Agneslundsvagen 27
212 15 Malmö, Sweden funded this trial.

What if I no longer want to participate in the trial at a later date?

You can revoke your consent at any time in writing or verbally without giving reasons and without incurring any disadvantages. If you wish to revoke your consent, please contact the trial management or the study staff supervising you. In the event of a revocation, you can decide whether the data collected from you for the trial should be deleted or may continue to be used for the purposes of the trial.

Even if you initially agree to further use, you can still change your mind later and request the deletion of the data. Please also contact the director of the trial or the staff treating you.

Please note that data that has already been included in scientific evaluations or data that has already been anonymized* can no longer be deleted at your request.

** "Anonymisation" is the changing of personal data in such a way that the person concerned can no longer be identified or can only be identified with a disproportionately large amount of time and money.*

Which data is collected and how is the data protected (data protection)?

Medical confidentiality and data protection regulations are observed. During the trial, medical findings and/or personal information will be collected from you and recorded in your personal file and/or stored electronically at the study center. The legal basis for the collection and processing of your data is your voluntary consent in accordance with the EU General Data Protection Regulation (EU-GDPR).
The data important for the trial are also stored in pseudonymised form**, evaluated and passed on to the trial management and data management (Prof. Dr. Th. Hackert and Institute for Medical Biometry (IMBI) Heidelberg).

***Pseudonymisation is the replacement of the name and other identification features with an identifier for the purpose of excluding or making it significantly more difficult to identify the person concerned (§3 Para. 6a BDSG).*

The trial management will take all reasonable steps to ensure the protection of your data in accordance with European Union data protection standards. The data is secured against unauthorized access.
The data collected during the study will be stored for 10 years after the end of the trial and then destroyed.
The data will be used for the stated purposes of this trial (see "Why is this study being conducted?") and possibly also for further research in the field of pancreatic surgery. You can restrict further processing beyond the study purposes.
You have the right to request information from the person responsible (see below) about the personal data stored about you (Article 15 GDPR). You can also request the correction of inaccurate data (Art. 16 GDPR) and the deletion (Art. 17 GDPR) of the data or the restriction of its processing (Art. 4 No. 3 and Art. 18 GDPR). You also have the right to data portability (Art. 20 GDPR). This means that the data will be made available to you in a machine-readable format.

The person responsible for the trial-related collection of personal data is:
Prof. Dr. Th. Hackert
Phone: +49 6221 56 5150
Email: thilo.hackert@med.uni-heidelberg.de

If you have any concerns about data processing and compliance with data protection requirements, you can contact the following data protection officer at the facility:
Data Protection Officer of the Heidelberg University Hospital
In Neuenheimer Feld 420
69120 Heidelberg
Datenschutz@med.uni-heidelberg.de

In the event of unlawful data processing, you have the right to complain to the following supervisory authority:
The state commissioner for data protection and freedom of information in Baden-Württemberg
PO Box 10 29 32, 70025 Stuttgart
Koenigstrasse 10a, 70173 Stuttgart
Phone: 0711/61 55 41 – 0
Fax: 0711/61 55 41 – 15
Email: poststelle@lfdi.bwl.de
Internet: http://www.baden-wuerttemberg.datenschutz.de

What happens to the results of the trial?

Ihre Daten werden in pseudonymisierter Form analysiert, in zusammengefasster Form publiziert und somit für andere Ärzte und zukünftige Patienten nutzbar gemacht.
Die von Ihnen zur Verfügung gestellten oder im Rahmen der Studie erhobenen Daten werden primär für die in dieser Informationsschrift dargelegten Fragestellungen verwendet. In Zukunft können jedoch weitere Untersuchungen mit diesen Daten erforderlich werden, die im Rahmen anderer Forschungsvorhaben behandelt werden. Die genauen Fragestellungen können jedoch zum derzeitigen Zeitpunkt noch nicht konkret benannt werden. Der Forschungszweck wäre jedoch auf die Pankreaschirurgie begrenzt. Diese künftigen Forschungsvorhaben werden von der jeweils zuständigen Ethikkommission separat beraten. Eine erneute Aufklärung und Einwilligung Ihrerseits wird nicht erfolgen.

New insights

The study doctor will inform you of any new findings that may affect the usefulness or safety of the study and thus your consent to participate in the study.

Do I incur any costs as a result of participating? Do I receive an expense allowance?
Participation in the trial is free of charge for you. However, you will not receive any expense allowance.

Do you have any further questions?

If you have any further questions about your illness, the surgical procedures used or the course of the trial, do not hesitate to ask your doctor. (S)He will be happy to answer these questions in detail.

Your study doctor:

Name: _____

Trial coordinator:
Dr. med. Thomas Pausch
Klinik für Allgemein-, Viszeral- und Transplantationschirurgie, Universitätsklinikum Heidelberg, Im Neuenheimer Feld 420, 69120 Heidelberg
Tel.: 06221/56- 5150

Further information on the study as well as information about the results and the outcome of the study can be obtained from the study center:

Clinical Study Center KSC

Department of General, Visceral and Transplantation Surgery Heidelberg University Hospital, Im Neuenheimer Feld 420, 69120 Heidelberg

ksc@med.uni-heidelberg.de, Tel.: 06221/56-36209

We thank you for your support.

One copy of this document is intended to remain with you, one copy will remain in the hospital.

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Declaration of Consent

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I was informed about the type, scope and importance of this clinical study in a detailed explanation. Among other things, Study objective and study duration, study-related requirements and possible risks in the context of study participation are discussed. I have received, read and understood the patient information and a copy of the declaration of consent. In this context, existing questions were discussed and answered.

The following questions / other aspects were also discussed:

_____

_____

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_____

No issues were discussed ☐

I am aware that this trial primarily serves to expand medical knowledge and may not bring any personal benefit to me.

I voluntarily agree to participate in the above trial. I had enough time to make my decision. I know that I can revoke my consent at any time without giving reasons and without any disadvantages for my further medical care.

Data protection

I am aware that personal data, in particular medical findings about me, are to be collected, stored and evaluated in this clinical trial. The data is processed in accordance with legal provisions and requires the following declaration of consent in accordance with Article 6 (1) (a) of the General Data Protection Regulation:

I have been informed about this and I voluntarily agree that my data collected in the trial, in particular information about my health***, can be recorded in pseudonymised form for the purposes described in the information sheet, evaluated and, if necessary, also passed on in pseudonymised form, only to countries that are subject to the data protection regulations of the European Union. Third parties do not have access to personal documents. My name will also not be mentioned when the results of the trial are published.

The personal data will be anonymised as soon as this is possible for the research purpose. The data will be kept for 10 years after graduation. Thereafter, all personal data will be deleted, provided that there are no legal, statutory or contractual retention periods to the contrary at this point in time.

The disease data collected as part of this study are documented on documentation sheets in paper form and on electronic data carriers and passed on pseudonymised for scientific evaluation to:

- Magle Chemoswed AB, Agneslundsvägen 27, 212 15 Malmö, Schweden.
- Dr. med. Thomas Pausch/Dr. med. Martin Wagner, Klinik für Allgemein-, Viszeral- und Transplantationschirurgie, Universitätsklinikum Heidelberg (Studienkoordinator, Datenmanagement).
- Institut für Medizinische Biometrie, Universitätsklinikum Heidelberg (Biometrie).

In addition, I agree that authorized representatives of the trial director, so-called monitors, who are sworn to secrecy, may inspect my personal data available from the study doctor, in particular my health data, insofar as this is necessary for checking the proper implementation of the study is necessary. For this measure, I release the study doctor from medical confidentiality.

I am aware that this consent can be revoked at any time in writing or verbally without giving reasons and without any disadvantages for me. This does not affect the lawfulness of the data processing that took place until the revocation. In this case, I can decide whether the data collected from me should be deleted or may continue to be used for the purposes of the trial.

I would like to limit the use of my data for other/future research purposes as follows:

_____

*** Pursuant to Art. 9 Para. 1 GDPR, health data is personal data of a special category, the processing of which must be expressly consented to by the trial participant.

Patient's first/last name (in block capitals)	Date of birth

Signature of the patient	Date (to be entered by the patient)

Informing and consent receiving person

I informed the patient about the aim and procedure of the trial as well as the risks during a conversation. I gave the patient a copy of the patient information and the declaration of consent.

Name of study doctor (in block capitals)	Date (to be entered by the study doctor)	Signature of the study doctor