Platelets and Complement activation during cardiopulmonary bypass craft surgery

Dear study patient,

We invite you to take part in the above investigation. The explanation about this takes place in a detailed medical discussion.

Your participation in this study is voluntary. You can withdraw from the study at any time without giving a reason. The refusal to participate or an early withdrawal from this study has no negative consequences.

Studies are necessary in order to obtain reliable new medical research results. An indispensable requirement for the implementation of a study, however, is that you declare your consent to participate in this study in writing. Please read the following text carefully as a supplement to the informational discussion with your investigator and do not hesitate to ask questions.

Please only sign the declaration of consent if you have fully understood the nature and process of this study, if you are willing to consent to participation and if you are aware of your rights as a participant in this study.

The responsible ethics committee issued a favourable opinion on this study, as well as on patient information and the declaration of consent.

What is the purpose of the study?

The number of open heart operations due to arteriosclerosis (calcium deposits in the blood vessels) using a heart-lung machine (HLM) has increased in number in recent years, so that "bypass surgery" is now considered a routine cardiac surgical procedure.

Nevertheless, there are some risks associated with this procedure and known complications, including postoperative bleeding.

With this study, we want to investigate how blood platelets in particular are activated by the heart-lung machine and how this affects the ability of the blood to clot.

We also want to investigate how the body's innate defence system (complement system), which is also activated by contact with the heart-lung machine, interacts with the blood platelets.

Since blood platelets are a very important component for intact blood clotting (haemostasis) and defence against infection, we hope to be able to draw conclusions and therapeutic options from the data obtained on how we can treat bleeding even better in the future.

How does the study work?

This study is taking place at the University Hospital Innsbruck. No study medication will be administered, only blood samples will be taken at 7 points in time, during and after your operation, with all blood samples taken from existing accesses.

The amount of additional blood taken can be regarded as harmless compared to the operation and the average blood loss there and amounts to 168.9 ml for the study period of 30 days.

The blood samples taken are then further processed and examined in the central laboratory and paediatric laboratory of the Innsbruck University Hospital.

We also record your basic data (height, weight, etc.), your previous illnesses and your premedication. During the study period, we record data at the time of study (visits) that describe your state of health and your recovery, which medication and transfusions are administered and the results of routine laboratory tests.

All data is only stored in encrypted form (indirect personal-related) without specifying your name, your initials or other information that allows conclusions to be drawn about you, using a patient number specially generated for this study and statistically evaluated. Only the study staff at the University Clinic for Anaesthesia and Intensive Care Medicine, Innsbruck, can use this number to find out your identity.

If there is still some blood left over after evaluating the parameters, these residual samples are frozen in order to carry out further tests in the hospital's own laboratory if further study-related questions arise at a later point in time.

The following measures are carried out exclusively for study reasons:

Blood draw at visit 0: 24.13 ml

Blood draw on visit 1: 24.13 ml

Blood draw on visit 2: 24.13 ml

Blood draw on visit 3: 24.13 ml

Blood draw on visit 4: 24.13 ml

Blood draw on visit 5: 24.13 ml

Blood draw on visit 6: 24.13 ml

Blood draw on visit 7: 24.13 ml

What are the benefits of participating in this study?

You are not expected to receive any health benefit from participating in this study. It is possible that you will benefit from the additional diagnostic measurements carried out. However, the results of this study may help to improve the treatment of patients undergoing this surgery in the future.

Are there any risks, complaints and side effects?

The amount of blood drawn is so small that there is no increased risk for you.

Does participation in the study have any other lifestyle effects and what are the obligations?

There is no other impact on your lifestyle. There are no obligations of any kind for you from participating in this study.

Information for women of childbearing potential - pregnancy test

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

When will the study be terminated early?

You can revoke your willingness to participate and withdraw from the study at any time, without giving reasons, without incurring any disadvantages.

Your investigator will promptly notify you of any new information that becomes known in relation to this study and that may become material to you. On this basis, you can reconsider your decision to continue participating in this study.

However, it is also possible that your doctor may decide to end your participation in this study prematurely without first obtaining your consent.

The reasons for this can be:

- You cannot meet the needs of the study
- Your investigator has the impression that further participation in the study is not in your interest
- the investigator makes the decision to discontinue the entire study or just to end your participation early

If you decide to withdraw from the study prematurely, there will be no check-up as there is no additional risk for you through participation.

How will the data collected in this study be used?

Regarding the data that is collected and processed about you in the course of this clinical trial, a basic distinction must be made between

1) those personal data by means of which you can be directly identified (e.g., name, date of birth, address, picture recordings ...),

2) Pseudonymised (encrypted) personal data in which all information that allows direct conclusions to be drawn about your identity is replaced by a code (e.g. a number) or (e.g. in the case of pictures) is made unrecognizable. This means that the data can no longer be assigned to your person without the need for additional information and without a disproportionate amount of effort

3) anonymized data, which can no longer be traced back to your person.

The encryption code is strictly separated from the encrypted data records and is only kept at your test centre.

The investigator and other employees of the trial centre who are involved in the clinical trial or your medical care have access to your unencrypted data. Data are protected against unauthorized access.

In addition, authorized representatives of the sponsor Medical University Innsbruck as well as representatives of domestic and / or foreign health authorities and the respective responsible ethics committees can inspect the unencrypted data, insofar as this is necessary to check that the clinical trial is being carried out properly.

The data is only passed on in encrypted or anonymized form. Only encrypted or anonymized data is used for any publications.

All persons who have access to your encrypted and unencrypted data are subject to the EU General Data Protection Regulation (GDPR) and the Austrian adaptation regulations in the currently applicable version when handling the data.

There are no plans to transfer data to countries outside the EU as part of this clinical trial.

You can revoke your consent to the collection and processing of your data at any time. After your revocation, no further data will be collected about you. The data collected up to the point of revocation can however be used in this clinical trial.

Due to the legal requirements, you also have the right to inspect your personal data and the possibility of correction if you discover errors, unless this is likely to make the conduct of the clinical trial impossible or seriously impaired.

You also have the right to lodge a complaint with the Austrian data protection authority about the handling of your data (www.dsb.gv.at).

In the case of a clinical trial under the Medicines Act, the right to data portability provided for in accordance with the GDPR is also invalidated by the provisions of the 2nd Data Protection Amendment Act 2018.

The expected duration of the clinical trial is until 31. January 2022. The duration of the storage of your data beyond the end 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, he or she can forward your request to the people responsible for data protection at the test centre.

Data protection officer of the Medical University of Innsbruck:

datenschutzbeauftragter@i-med.ac.at

Data protection officer at Tirol Kliniken GmbH:

datenschutzbeauftragte@tirol-kliniken.at

Are there any costs for the participants? Is there a reimbursement or compensation?

You will not incur any additional costs by participating in this study.

Opportunity 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 study. We will also be happy to answer questions relating to your rights as a study patient and participant in this study.

Contact person name: Ao. Univ.-Prof. Dr. Judith Martini

Available at: +43 512 504 80478

You can also call the “University Clinic for Anaesthesia and Intensive Care Medicine” on + 43 / 512-504-22403 and have the doctor on duty put you through if you cannot reach the above-mentioned people.

External contact points

If you have any further questions about the declaration of consent, you can also contact the Tyrolean patient representative:

Tyrolean patient representation

Mr. Mag. Birger Rudisch Telephone: +43 (0) 512 508 7700

Tyrolean patient representatives Fax: +43 (0) 512 508 747705

Meraner Strasse 5 (1st floor) email: patientenvertretung@tirol.gv.at

A-6020 Innsbruck http://www.tirol.gv.at/patientenvertretung

Brief summary

What is the purpose of this study?

To study the reaction of platelets in interaction with the innate immune system during activation by the heart-lung machine.

How many people will take part in the study?

190 volunteer participants.

Why am I suitable for participation?

Voluntary patient who has to undergo cardiac surgery on the coronary arteries

What can I expect if I take part?

Several blood samples will be collected during the operation and during the first to the third postoperative day.

What benefits may I have from participating?

It is possible that the laboratory tests performed as part of the study provide more information about your health.

What are the risks and inconveniences involved?

There are no additional risks associated with participating in this study, except for a slight loss of blood totalling 168.9ml during the operation (corresponds to approx. 3 teaspoons of blood per 1 study sample)

Declaration of consent

Name of the study patient in block letters: ....

Date of birth: .....

Code: .....

I agree to participate in the PAC study

"Platelets and complement activation during coronary artery surgery (" PAC ")"to participate.

I have been informed in detail and comprehensibly about the nature, meaning and scope of the study and the requirements arising from it. I have also read the text of this study patient information and declaration of consent, which comprises a total of 8 pages. Any questions that arose were answered comprehensibly and adequately by the investigator. I had enough time to make up my mind. I have no further questions at the moment.

I will follow the medical instructions required to carry out the study, but I reserve the right to terminate my voluntary participation at any time without incurring any disadvantages.

Should I withdraw my participation in this study or if my participation in the study is prematurely terminated by the sponsor or the investigator, I agree that the data collected up to this point may continue to be used.

I agree that my residual blood samples will only be stored with indirect, personal labelling and processed in the hospital's own laboratory if further questions regarding my blood coagulation / complement system arise during the study:

☐ yes ☐ no

However, I reserve the right to revoke this consent at any time and without giving reasons and to request the immediate destruction of my samples.

After the data protection clarification, I give my express consent that my personal data can be used by the examiner Dr. Judith Martini and her employees are processed and, if necessary, passed on to domestic and foreign health authorities.

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

....

(Date, name and signature of the study patient)

....

(Date, name and signature of the responsible investigator)