Patient Information and Informed Consent for Participation in a Clinical Trial

Copeptin - Relevance as a perioperative marker in pediatric cardiac surgery

Dear parents,

We would like to invite your child to take part in our clinical trial about Copeptin. You will be informed about the details of the study in a medical consultation.

The participation in this clinical trial is voluntary. Withdrawing from the trial is possible at any time without stating any reason and has no disadvantages for the further medical care of your child.

Clinical trials are essential to gain new medical research findings. To conduct a clinical study, it is essential for you to sign this patient information as a declaration of consent. Please read the following text in addition to the medical consultation and do not hesitate to ask any questions.

Please sign the declaration of consent only if

- you understood the procedure of the clinical trial entirely,
- you are ready to agree to participate,
- you know about your rights as a participant in this clinical study.

The Ethical Review Committee of the Medical University of Vienna obtained approval for this clinical study and the patient information.

1. What is the objective of this clinical study?

The aim of this study is to investigate the significance of a blood value as a control value in patients with congenital heart disease undergoing cardiac surgery. The analyzed lab value is named Copeptin. It has proved its usefulness in cardiac diseases in previous studies. The findings of this trial may help to improve therapy and follow-up after congenital heart surgery.

2. Course of the clinical study:

This clinical study will be carried out in our hospital.

Three blood samples will be drawn. This will be done at the times of the routine blood sampling. Therefore, there will not be any additional stress for your child. The amount needed per blood sample is very low (0.9ml per blood sample). The first two blood samples will be drawn at the day of surgery (before and after surgery in the operating room). The last blood sample will be drawn on the first postoperative day at the intensive care unit. After the third blood sample the participation in the study will be finished for your child. In total 81 patients will be included in this study.

3. Are there any benefits for the participants in this clinical trial?

There will be no benefit for the individual patient participating in this clinical trial. In the future Copeptin values may be used routinely and may improve the medical care for your child as well.

4. Are there any risks, complaints and side effects to be expected?

Since the blood samples will be drawn from the central venous catheter it is ensured that there are no additional interventions beside the routine activities. Therefore, no risks, complaints or side effects are to be expected.

5. In what case will the study be finished earlier than planned?

Withdrawing from the trial is possible at any time, without stating any reason. This has no disadvantage for the further medical care of your child.

You will be informed immediately about any essential findings regarding the trial relevant to your child's participation. Based on this information you can then decide about the further participation in the clinical trial.

It is also possible for the responsible doctor to terminate the study earlier than planned without seeking your agreement. Reasons for this may be:

a) the patient meets no longer the inclusion criteria of the clinical trial;

b) the responsible doctor may have the impression that it is not in your interest to participate in the trial any further.

6. In which way will the data collected in this study be used?

Only the responsible doctor and her coworker in this study will have access to the private data of the patients. These people are bound by the obligation to confidentiality duty.

The data will be shared solely for statistical purposes. Your child will never be mentioned by name. In publications of the data of this clinical study, your child will not be mentioned by name.

7. Are there any expenses for the participants? Is there reimbursement or any rewards?

There are no expenses and no claim for compensation for the participants in this study.

8. For any further questions:

The responsible doctor and her coworkers are available for any further questions regarding this clinical trial.

Name of the responsible doctor:	Dr. Claudia Herbst
Phone number:	0140400-56200
Name of the coworker:	Erhan Urganci (student)
Phone number:	+43 (0)650 3407292

9. Informed consent

Name of the patient: .....

Date of birth: ..... Code: .....

I give my consent that my child is allowed to participate in the Copeptin trial.

I was informed in detail about the Copeptin trial and its possible risks, side effects and requirements of the study by Dr. Claudia Herbst/ Erhan Urganci (student). I have read the text of this patient information and the informed consent. All questions were answered in an understandable and detailed way by the responsible doctor. I had enough time to decide about having my child participate in this study and have no further questions.

I will follow the instructions needed to carry out the trial and reserve the right to revoke my consent to the study without causing any disadvantages for the further medical care of my child.

I agree with the data obtained from the study to be recorded. For verification purposes, representatives from responsible authorities are allowed to inspect the personal medical data of the patients.

The terms of the data privacy act will be strictly adhered to.

I received a copy of the patient information and informed consent. The original remains with the responsible doctor.

.....
(date and signature of parents)

.....
(date, name and signatur of the responsible doctor)