Title of the study

Treatment of medial femoral neck fractures – anterolateral versus direct anterior approach

Date: 12-21-2015

Patient information and declaration of consent to participate in the prospective observational study

Treatment of medial femoral neck fractures – anterolateral versus direct anterior approach

Dear participant!

We invite you to take part in the abovementioned prospective observational study. The explanation about this takes place in a detailed discussion.

Your participation in this study is voluntary. You can withdraw from the participation at any time without reason. The refusal to participate or an early withdrawal from this study will not have any negative consequences on your medical treatment.

Observational studies are studies in which, as a rule, only data are recorded and evaluated during the context of usual patient care. In some cases, additional, non-stressful examinations or surveys may also be carried out. In no case the treatment intended for you will be changed by your participation in the study. Observational studies are necessary to gain additional knowledge about already renowned medical practices.
The responsible ethics committee issued a positive statement on this observational study, as well as on patient information and the declaration of consent.

1. What is the purpose of this study?

The purpose of this observational study is to determine the differences between the anterolateral to the direct anterior approach after medial femoral neck fracture.

2. How does the observational study work?

This study is being carried out at our clinic and there will be a total of approximately 60 people. Your participation is expected to last one year.

The following measures are carried out exclusively for study reasons:

No additional interventions are carried out, only data, that arise as part of your medical care, are recorded and evaluated.

3. What are the benefits of participating in the observational study?

You are not expected to receive any health benefit from participating in this study, but future patients with the same condition may benefit from the results.

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

No.

5. How will the data collected in this observational study be used?

Unless otherwise provided by law, only the study physicians and their staff have access to the confidential data in which you are named ("personal" data). Furthermore, representatives of domestic and foreign health authorities, the responsible ethics committee and persons who were commissioned by the study director and / or client of the study to control the data quality can inspect this data in order to check the accuracy of the records. These persons are bound to secrecy.
The data is passed on exclusively for statistical purposes and without exception you will not be named. You will also not be named in any scientific publications of the data from this study.
The provisions of the data protection act in the current version are complied with.

6. Opportunity to discuss further questions

Your study doctor and her staff will be happy to answer any further questions you may have in connection with this study.

Name of contact person: Dr. Renate Krassnig

Always available at: +43 315 385 81972

7. Declaration of Consent

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

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

I have read and understood this information sheet. All of my questions have been answered and I have no further questions at the moment.
With my personally dated signature, I hereby give my voluntary consent that my data may be stored and used for scientific purposes without direct personal reference. I am aware that representatives of the responsible authorities and the ethics committee, as well as persons entrusted with the control of the data quality, may inspect my personal illness data to check the accuracy of the data recording.
I know that I can revoke this consent at any time and without giving reasons.
I have received a copy of this patient information and declaration of consent. The original remains with the study doctor.

....

(Date and signature of the patient)

....

(Date, name and signature of the physician)