Information of participants and declaration of consent to participate in clinical trial

Title: Continuous wound infiltration after hallux valgus surgery

We invite you to participate in the clinical trial mentioned above. All essential information will be provided in a detailed discussion with your surgeon.

Your participation in this clinical trial is voluntary. You can quit at any time without explanations. Disapproval of participation or withdrawal before the end of this study will not affect medical care.

Clinical trial are essential to obtain reliable medical results in research. A signed declaration of consent to participate in a clinical trial is a mandatory condition of every clinical trial. In addition to the medical consultation please read these following pages thoroughly and do not hesitate to ask questions.

Please sign this declaration of consent only

- If you have fully understood the kind and course of the trial
- If you are willing to approve to participation and
- If you are aware of your rights as a participant of this clinical trial.

This clinical trial as well as the information of participants and the declaration of consent has been approved by the Ethic Commission on Jan. 30, 2014.

1) Information about diagnosis:

Hallux valgus is an often painful deviation of axis of the big toe, which requires surgical correction in many cases. These corrections are frequently performed and case local pain especially within the first 24 hours after surgery. We want to reduce these pains by continuous local wound infiltration additional to regular pain therapy and thus provide faster and less painful recovery to patients in the future.

2) Description of the subject of trial:

In continuous wound infiltration a catheter is being inserted at the operation site at the end of the operation and a local anesthetic agent is being administered. This procedure has been successfully been performed several other operations sites. The effectiveness of this procedure will now be examined also in 40 cases of hallux valgus surgery in this study.

3) Notification of course of trial

This clinical trial will be carried out at our department und will include about 50 persons. Your participation in this clinical trial will last for 6 weeks.

In this clinical trial the effect of administration of local anesthetic agent (Ropivacaine 2mg/ml) will be compared to a so called placebo. A placebo is a similar looking substance (saline solution) without pharmacologic agent. In both cases a small catheter will be inserted in the operation site and one of the two substances will be administered at a rate of 2 ml/h for the first 24 hours after surgery. Which of the substances you receive is accidental (randomization). The probability to receive a placebo is 50%. Neither you nor the examiner know which substance is been used (double blinded). If necessary the examiner can find out at any time which substance you receive.

No matter whether you participate in this trial or not a lot of examinations and controls will be performed in the course of your treatment. They will be explained to you by your examiner when he talks to you prior to surgery. Except for filling in a questionnaire before and after surgery the participation in the study does not cause additional trouble or costs. All data needed for the study will be obtained during the stay in the hospital and the regular follow-ups after dismissal. It is essential for the success of this study to follow the instructions of the examiner and to come to the follow-ups as dated.

4) Notification of general and personal benefit as well as risks and side effects:

Continuous wound infiltration – in addition to regular pain therapy -could lead to reduction of postoperative pain. It is also possible that you may not benefit from your participation in this clinical trial. The advantage of the method is that administration of local anesthetic has only few effects on the rest of the body. Possible side effects of Ropivacaine are lowering / elevation of blood pressure or heartbeats, dizziness, headaches, nausea and vomiting, itches or fever. Sudden life-threatening allergic reactions are rare (1-10 of 10.000 persons treated). Other severe side effects as caused by overdose, include problems in speaking, muscle tics, trembling, seizures and loss of conscience. There is no evidence in trials so far that even higher doses would lead to more complications. The inserted wound catheter could lead to a higher rate of local infections. The assessment of the head of study as well as the Ethic Commission was favorable concerning benefit- risk ratio.

5) Information of limitation of duration of trial:

To avoid falsification of results it is not allowed to take pain medication other than provided. There are no further limitations. In case of severe complications (e.g. severe allergic reaction) it is possible to abolish blinding of the substance used at any time.

6) Notification about pregnancy / risks in fertile males:

Females can only participate in this trial if pregnancy is excluded by medical certification. During the trial a reliable method of birth control should be used, please ask your doctor about it. A pregnancy test at the end of the trial is recommended. It is not evident so far if Ropivacaine does have influence on pregnancy or lactation. There is also no evidence so far if there is any influence on the fertility of males. Please inform the examiners immediately if you got pregnant during the ongoing trial or suspect it.

7) Information about insurance on personal injury:

As a participant in this trial you are enrolled in personal injury insurance as required by law (§ 32 medication law) covering all injuries of your life and health as caused by procedures during examinations in this trial; except for genetic damages. The insurance was taken out by Zurich Cosmos Insurance Company (Schwarzenbergplatz 15, 1010 Wien, Tel. +43 1 50125-0; policy number: 07108763-1) and can be examined if you like. In case of injury you can contact the insurance company yourself and claim for compensation. The insurance contract is subjected to Austrian law and statements of claim have to be made in Austria. For support you can turn to the representation of patients.

In order not to put at risk the coverage of the insurance you should

- contact your examiner to approve another medical treatment (except in case of emergency). This is also necessary for additional medication or participation in another trial.
- contact the examiner – or the insurance company mentioned above – immediately in case of injury if it may be caused by clinical trial
- contribute to solve the reason, course and consequences of the case and try to reduce the extent of damage. This includes the permission to provide information to the insurance for all medical doctors involved if required.

We want you to know that the insurance does not cover accidents on the way to or from the participation in this study, except if caused by a substance used in the trial.

8) Comment on privacy of data:

Personal data may be used in this trial only with consent of the participant. Normally only the examiner and his staff or staff of health departments involved (local or abroad) have access to personal data. All persons who have access to personal data for professional reasons are restricted by law to secrecy (§ 15 DSG) beside other duties. Data of this study will be turned in to the client fundamentally in an indirectly personal or anonymous way. Besides that data will only transmitted anonymously to meet statistic requirements. Publications of data of this trial will also be anonymously.

Also in case you have already approved without pressure and in recognition of the facts that your personal data in this study may be used, you can still withdraw your approval without explanations or adverse effect of your medical treatment. In case of withdrawal your personal data cannot further be used. Withdrawal is usually combined with exclusion of the study. We would especially like to refer to legal regulations, especially §§ 46. 47 AMG and §§ 55, 56 MPG, as far as preservation, documentation and the duty to provide certain data are concerned.

9) Information about voluntariness and possibilities of early termination:

Your participation in this study is voluntary. You can withdraw at any time without explanation. Disapproval or early withdrawal has no adverse effect on medical care. Your examiner will inform you immediately about latest results of this study that could be relevant for you. Thus you can reconsider further participation. If you decide to withdraw or one of reasons mentioned above leads to exclusion from the study, a regular follow-up examination will be necessary for your own safety.

It is also possible, that the examiner (or the client of the trial) decides to exclude you from participation without your approval. Reason could be:

- You cannot meet the requirements of the clinical trial
- the examiner has the impression further participation is not beneficial for you
- the client decides to terminate the entire clinical trial or your participation only.

10) Information about contact and availability:

Should you have any questions about the declaration of consent, you are welcome to contact the representative of patients: Herr Mag. Birger Rudisch / Tiroler Patientenvertretung / Meraner Straße 5, I. Stock / A-6020 Innsbruck / Tel. +43 (0)512-508-7700 / E-mail: patientenvertretung@tirol.gv.at

Einwilligung:

I have read and fully understood the information for participants and declaration of consent. All my questions have been answered and I do not have further questions. In case I have further questions during the trial I can turn to PD Dr. Rainer Biedermann (+43 512 504-80315)

After legal information about protection of data I agree that my personal data may be used in the course of this study by the examiner (PD Dr. Rainer Biedermann) and his staff as well as to the transmission to local or foreign health departments if required.

I hereby declare my consent to participate in this study. I have received one copy of this declaration of consent, the original version remains with the examiner.

Innsbruck,	Innsbruck,
_____	_____
Name of participant:	Name of medical doctor:
_____	_____
Signature of participant:	Signature of medical doctor:

One copy of this declaration and information sheet will be handed over.