Information sheet for participants in the study

Dear patient, we are currently carrying out research on your pain experience during suturing an open wound. At the university hospital of Brussels, there are two standard options to get local anesthesia before suturing. We investigate which option prevails in pain experience during suturing.

The results of this study can be used in future to recommend the best option and to minimize pain in other patients.

Introduction

Study: Lidocaine adrenaline tetracaine gel (LAT-gel) vs lidocaine infiltration in laceration repair: a comparative trial in adults

Goal: We would like to examine whether or not the pain experience for you and other patients of the same anesthesia option is different from the patients who got the other option. After seeing a treating physician, who will further decide on your personal treatment plan, which will not be different by participating in this study. Your doctor may ask you to indicate your pain on a scale, and will note down information about you, the wound and the suture. This information will be obtained by consulting your patient record.

If you take part in this study, you should be aware that:

- The treatment offered to you by the investigator in accordance with current recommendations will not be altered if you take part in the study.
- This clinical study is being conducted after having been reviewed by one or more ethics committees.
- Your participation is voluntary and must remain free from any coercion. It requires the signature of a document expressing your consent. Even after having signed this document, you can stop taking part by informing the investigator.
- The data collected on this occasion are confidential and your anonymity is guaranteed during publication of the results.
- Insurance has been taken out in case you should suffer any damage in connection with your participation in this clinical study.
- There are no risks, costs or reimbursement involved in your participation.

Contact

If you need further information, but also if you have problems or concerns, you can contact the investigator (Stiers Jonas) or a member of his research team (Dr. Clinckaert Carol or Dr. prof. Hubloue Ives) on the following telephone number (02 477 51 00).

Informed consent

I declare that I have been informed of the nature of the study, its purpose, its duration, the possible side effects and what is expected of me.

I have had the opportunity to ask any questions that came to mind and have obtained a favourable response to my questions.

I understand that data about me will be collected throughout my participation in this study and that the investigator and the sponsor of the study will guarantee the confidentiality of these data.

I agree to my personal data being processed as described in the section dealing with confidentiality guarantees.

I agree/do not agree (delete as appropriate) to the research data collected for the purposes of this study being processed at a later date provided this processing is limited to the context of the present study (better understanding of the disease and its treatment).

I have received a copy of the information to the participant and the informed consent form.

Surname and first name date signature

Guarantee of confidentiality

Your participation in the study means that you agree to the investigator collecting data about you and to the study sponsor using these data for research purposes and in connection with scientific and medical publications.

You are entitled to ask the investigator what data are being collected about you and what is their use in connection with the study. This data concerns your current clinical situation but also some of your background, the results of examinations carried out within the context of care of your health in accordance with current standards. You have the right to inspect these data and correct them if they are incorrect1.

The investigator has a duty of confidentiality vis-à-vis the data collected.

This means that he/she undertakes not only never to reveal your name in the context of a publication or conference but also that he/she will encode your data before sending them to the manager of the database of collected data. Data are collected and administered by Jonas Stiers using a spread sheet application: Excel.

The investigator and his/her team will therefore be the only ones to be able to establish a link between the data transmitted throughout the study and your medical records[2].

The personal data transmitted will not contain any combination of elements that might despite everything allow you to be identified3.

For the study data manager designated by the sponsor, the data transmitted will not allow you to be identified. The latter is responsible for collecting the data gathered by all investigators taking part in the study, processing them and protecting them in accordance with the requirements of the Belgian law on the protection of privacy.

To verify the quality of the study, it is possible that your medical records will be examined by third parties (ethics committee, representatives of the study sponsor, external auditors). In any event, this may only take place under the responsibility of the investigator or of one of his/her colleagues and by persons subject to the obligation of professional secrecy.

These (encoded) data will be able to be sent to Belgian or other regulatory authorities, to the relevant ethics committees, to other doctors and/or to organizations working in collaboration with the sponsor.

Your consent to take part in this study therefore also implies your consent to the use of your encoded medical data for the purposes described in this information form and to their transmission to the aforementioned people and authorities.

The sponsor undertakes only to use the data collected within the context of the study in which you are taking part.

If you withdraw your consent to take part in the study, to guarantee the validity of the research, the data encoded up to the point at which you withdraw will be retained. No new data may be sent to the sponsor.

Insurance

In an observational study, the only possible risk would be a flaw in the measures taken to protect the confidentiality of the private information about you. Even without fault, the sponsor accepts responsibility for damage caused to the participant (or his/her dependants) and linked directly or indirectly to participation in this study. In this context, the sponsor has taken out an insurance contract (Ethias, polisnummer, Katelijne Delmal, legal counsel, Katelijne.Delmal@uzbrussel.be)[4].

1 These rights are guaranteed by the Law of 8 December 1992 on the protection of privacy in relation to the processing of personal data and by the Law of 22 August 2002 on patient rights.

[2] For clinical studies, the law requires this link with your records to be retained for 20 years.

3 The database containing the results of the study will therefore not contain any combination of elements such as your initials, your gender and your full date of birth (dd/mm/yyyy).

[4] Conform artikel 29 van de Belgische wetgeving inzake experimenten op de menselijke persoon (7 mei 2004)