Subject information for participation in medical research

Laatste twee pagina's door patiënt/vertegenwoordiger laten tekenen en bewaren op SEH!

Outcomes after nail luxations

Introduction

Dear Sir/Madam,

This letter asks whether you would like to take part in medical research. Participation is voluntary. You are receiving this letter because you had a nail luxation (displacement). It explains the study, what it means for you, and the advantages and disadvantages. It is a lot of information. Please read it carefully and decide whether you would like to participate. If so, you can complete the consent form.

Ask your questions

You can make your decision using the information in this letter. We also advise you to:

- Ask questions to the researcher who gives you this information.
- Talk about this study with your partner, family, or friends.
- Read the information at www.rijksoverheid.nl/mensenonderzoek.

1. General information

OLVG has initiated this study. Below, OLVG is referred to as the "sponsor".

2. What is the purpose of the study?

In this study we assess the cosmetic and functional outcomes of fingernail luxations. We also examine whether the type of treatment given influences these outcomes.

3. What is the background of the study?

A nail luxation (the nail becoming detached from the nail bed) often occurs after trauma to the finger. At present, the best treatment is not yet known. Some doctors replace the nail in the nail bed, while others choose not to do so. The treatment choice often depends on the doctor's preference. In this study we want to investigate which treatment method gives the best result. In doing so, we look not only at nail healing, but also at finger function and the final appearance of the nail.

4. How will the study be carried out?

How long will the study last?

If you take part in the study, you will complete questionnaires four times in total. Each time this will take about 5 to 15 minutes.

Examinations and measurements

After the injury, you will return to the hospital three times:

- 3 to 5 days after the injury
- 2 weeks after the injury
- 6 months after the injury

During these visits we will ask you to complete questionnaires. This will also take about 5 to 15 minutes each time.

What is different from usual care?

The follow-up visits at 3 to 5 days and 2 weeks after the injury are part of standard care. For the study, we schedule one extra appointment: 6 months after the injury. This extra check is intended to assess how well finger function and the nail have recovered.

5. What agreements do we make with you?

We would like the study to proceed smoothly. We therefore ask you to agree to the following. You contact the researcher in the following situations:

- o You no longer wish to take part in the study.
- o Your telephone number, address, or email address changes.

6. What are the advantages and disadvantages of taking part in the study?

Taking part in the study may have advantages and disadvantages. By participating, you help researchers gain more insight into the treatment of nail luxations. A disadvantage is that participation takes time.

7. What happens after the study?

Will you receive the results of the study?

About 12 months after your participation, the researcher will inform you of the main results of the study. If you do not want to know this, please tell the researcher. He will then not tell you.

8. What do we do with your data?

If you take part in the study, you also give permission for your data to be collected, used, and stored.

Which data do we store?
We store the following data:
- your name
- your sex
- your email address
- your date of birth
- data about your health
- your answers to the completed questionnaires

Why do we collect, use, and store your data?
We collect, use, and store your data to answer the research questions of this study and to publish the results.

How do we protect your privacy?
To protect your privacy, your data will be given a code. Only this code will appear on your data. The key to the code is kept in a secure place in the hospital. When we process your data, we use only that code. Also in reports and publications about the study, nobody will be able to trace that the data were about you.

Who can view your data?
Some persons can see your name and other personal data without the code. These are people who check whether the researchers perform the study properly and reliably. These persons may access your data:
• Members of the committee that monitors the safety of the study.
• A monitor working on behalf of OLVG.
• National and international regulatory authorities

These persons will keep your data confidential. We ask your permission for this access.

How long will we keep your data and body material?
We keep your data at OLVG for 10 years.

Can you withdraw your consent for the use of your data?
You can withdraw your consent for the use of your data at any time. Please note: if you withdraw consent after researchers have already collected data for the study, they may still use those data.

Would you like to know more about your privacy?

- Would you like to know more about your rights regarding the processing of personal data? Please visit www.autoriteitpersoonsgegevens.nlwww.autoriteitpersoonsgegevens.nl.
- Do you have questions about your rights? Or a complaint about the processing of your personal data? Then contact the person responsible for processing your personal data. For this study that is:
    - OLVG. See appendix A for contact details and website.

- If you have complaints about the processing of your personal data, we advise you to first discuss them with the research team. You can also contact the Data Protection Officer of OLVG or file a complaint with the Dutch Data Protection Authority.

9. Will you receive compensation if you participate in the study?

Participation in the study will cost you nothing. You will also not receive compensation for taking part in this study.

10. Are you insured during the study?

You are not additionally insured for this study, because participation does not involve extra risks. Therefore OLVG does not have to take out extra insurance.

11. Do you have questions?

Questions about the study can be asked to Drs. M. Brouwer. Do you have a complaint? Then discuss this with the researcher or the doctor treating you. Would you prefer not to? Then contact the complaints officer of OLVG. Appendix A explains how to reach them.

12. How do you give consent for the study?

You may first take time to think about this study. Afterwards, you tell the researcher whether you understand the information and whether you do or do not want to participate. If you want to participate, complete the consent form. Both you and the researcher will receive a signed copy of this consent declaration.

Thank you for your time.

16. Appendices to this information

A. Contact details OLVG
B. Consent form participant
C. Consent form representative

Appendix A: contact details OLVG

Researcher:
M. Brouwer, MD
Email address: m.brouwer2@olvg.nl

Appendix B: consent form participant

Please have this form signed by the patient, and keep it at the ED!

Outcomes after nail luxations

- I have read the information letter. I was also able to ask questions. My questions have been answered well enough. I had enough time to decide whether I want to participate.
- I know that participation is voluntary. I also know that I can decide at any time not to participate after all, or to stop. I do not have to explain why I want to stop.
- I give the researchers permission to collect and use my data. The researchers will do this only to answer the research question of this study.
- I know that for monitoring of the study some people may inspect all my data. These people are listed in this information letter. I give these people permission to inspect my data for this monitoring.
- I want to participate in this study.

Patient

My name is (participant): ……..

Signature: ……. Date : __ / __ / __

Healthcare professional

Additional information was given by:

Name:……..

Position:…….

Signature:……. Date: __ / __ / __

Researcher (M. Brouwer)

I declare that I have fully informed this participant about the above-mentioned study.

If information becomes available during the study that could influence the participant's consent, I will inform this participant in time.

Name of researcher (or representative):…….

Signature:……. Date: __ / __ / __

(If applicable) - Appendix C: consent form representative

Please have this form signed by the representative, and keep it at the ED!

Outcomes after nail luxations

- I have been asked to give consent for this person to participate in this medical scientific study:
- I have read the information letter for the participant/representative. I was also able to ask questions. My questions have been answered well enough. I had enough time to decide whether I want this person to participate.
- I know that participation is voluntary. I also know that I can decide at any time that this person will not participate after all. I do not have to say why I want this.
- I give the researchers permission to collect and use this person's data. The researchers will do this only to answer the research question in this study.
- I know that for monitoring of the study some people may gain access to all of this person's data. These people are listed in this information letter. I give these people permission to inspect this person's data for this monitoring.
- I agree that this person will participate in this study.

Patient

Name of participant: …….. Date of birth: __ / __ / __

Representative

Name of legal representative:……

Relationship to the participant: ……

Signature: …… Date: __ / __ / __

Healthcare professional

Additional information was given by:

Name:……..

Position:…….

Signature:…… Date: __ / __ / __

Researcher (M. Brouwer)

I declare that I have fully informed the person/persons above about the above-mentioned study. If information becomes available during the study that could influence the representative's consent, I will inform him/her in time.

Name of researcher (or representative):……

Signature: …… Date: __ / __ / __