Information form for ages 12–16

Have the last two pages signed by the patient/representative and keep them in the Emergency Department!

Outcomes after nail luxations

Are you taking part in a study? Here you can read more about the study and your rights. Read this carefully so you know what you are deciding about. You may take your time before deciding.

Your parents will also receive information about this study. You can talk with them about the study. Together with you, they will make a decision.

Questions and contact

Do you have questions? Discuss them with your parents. Or ask them to the researcher. You can write your questions below.

You can also always email the researcher: m.brouwer2@olvg.nl

Space to write down your questions:

Tip: take a picture of your questions so you have them with you when you talk to the doctor/researcher.

About the study

This study takes place at OLVG in Amsterdam. The aim is for about 100 children to take part in the study. The study has been reviewed and approved. The name of the committee that assessed it is: ACWO

Why this study?
This study is important because doctors still do not know well what the best treatment is for nail injuries at the fingertip. Often the nail is put back, but this takes time, can be painful, and can sometimes be hard on children. Maybe this is not necessary and the finger heals just as well without replacing the nail. With this study we want to find out which treatment is really the best.

Background
Sometimes a nail becomes loose or crooked after an accident involving your finger. Doctors often put that nail back, but this can be painful, take a long time, and sometimes you even have to be put to sleep for it. We do not really know whether that is always necessary. With this study we want to see whether the finger also heals well without putting the nail back.

How does taking part work?
If you come to the Emergency Department with a nail injury, we ask you and your parents whether you want to take part. If you want to participate, the doctor may choose (together with the patient) whether or not the nail is put back. We will see you again at the hospital a few more times: after a few days, after two weeks and after six months.

About the treatment

The doctor chooses, together with the patient, between:

1. Replace the nail: The nail is put back on your finger. This may hurt a little and takes longer. Sometimes you need an injection or you are put to sleep so that you do not feel anything.
2. Do not replace the nail: The nail is not put back. The wound is cleaned and dressed so that your finger can heal quietly.

After that you will come back to the hospital a few more times so we can see how your finger is doing: after a few days, after two weeks and after six months. A visit is usually short, about fifteen to twenty minutes. During these visits questions are asked using questionnaires that the doctor enters into your file. The finger is also examined. This is standard care and is not only necessary because you are taking part in the study.

With this study we want to see whether the finger heals just as well and looks just as good without putting the nail back.

Discomforts
When the nail is not replaced there are actually no extra discomforts, because the treatment with ointment and dressings causes less discomfort. When the nail is replaced there may be discomforts such as local anaesthesia with a needle in the finger, or (in young children) sedation that makes you sleepy so the nail can be replaced.

Important to know

- You and your parents may always decide for yourselves whether you take part.
- You may stop at any time, without giving an explanation.
- Your data will be stored safely and only viewed by the research team.

Advantages and disadvantages
The advantage is that we can investigate whether your finger heals just as well without needing to put the nail back. In the future this may save pain and time for other children.

Compensation
You will not receive money for taking part. The extra check-ups do not cost your parents anything.

Your rights

Do you have to take part?
No, you may decide for yourself whether you want to take part. If you do not want to participate, you do not have to, even if your parents would prefer that you do. If you want to participate, sign the form. Even after that, you may still stop whenever you prefer not to continue. Do tell the researcher. You do not have to explain why you are stopping.

Withdrawing consent
If you want to stop, tell the researcher. This is called withdrawing your consent. The information already collected will still be used for the study.

Your data
For the study we need two things that belong to you:

Personal data = information about who you are, for example your date of birth and where you live.



Medical data = (also a kind of personal data) information about your health, for example whether you are ill and whether you use medicines.



These two things are needed to carry out the study. Your parents give permission for us to use them. Do you want to know more about exactly what we do with your data? Ask your parents; it is written in their information letter. You can also ask the researcher.

Your decision

The form

If you want to take part, sign the consent form (Appendix B). We also need a signature from both of your parents/guardians (Appendix C)

You can also choose whether we may ask you later about another study. We will then give you information about the new study, and you can decide whether you want to take part.

Information for parents

Introduction

Dear Sir/Madam,

With this information letter we would like to ask whether you would like your child to take part in medical scientific research. Participation is voluntary. You are receiving this letter because your child has had a nail luxation (displacement). Here you can read what the study is about, what it means for your child, and what the advantages and disadvantages are. It is a lot of information. Would you please read it and decide whether you want your child to take part? If so, you can complete the consent form.

Please ask your questions
You can make your decision using the information in this letter. In addition, we recommend that you do the following:

- 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 set up this study. Below, we will refer to OLVG as the 'sponsor'.

2. What is the purpose of the study?
In this study we look at the cosmetic and functional outcomes of finger nail luxations. We also look at whether the type of treatment that is given has an effect on this.

3. What is the background of the study?
A nail luxation (the nail coming loose from the nail bed) often occurs after trauma to the finger. At present it is not yet known what the best treatment is. The standard treatment is to put the nail back. This makes the treatment in the Emergency Department longer and requires local anaesthetic with a needle, or even sedation in young children, making the child sleepy. In this study, the doctor may choose the treatment together with the patient (whether or not to replace the nail). In this study we want to find out which treatment method gives the best result. We are looking not only at nail recovery, but also at finger function and the final appearance of the nail.

4. How will the study be carried out?
How long does the study last?
If your child takes part in the study, your child will answer the questions (with your help) during the outpatient visits. The outpatient appointment takes about 20 minutes.

Tests and measurements
After the injury, your child will come back to the hospital three times:

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

- 6 months after the injury
  During these appointments we ask your child to answer the questions with your help and we examine the finger.

What is different from usual care?
The check-ups 3 to 5 days, 2 weeks and 6 months after the injury are part of standard care.

5. What agreements do we make with you?
We would like the study to proceed smoothly. Therefore, we ask you to agree to the following:
• You contact the researcher in the following situations:
  o You no longer want your child to take part in the study.
  o Your telephone number, address, or email address changes.

6. What are the advantages and disadvantages if your child takes part in the study?
Taking part in the study may have advantages and disadvantages. By participating, your child helps the researchers gain more insight into the treatment of nail luxations. A disadvantage of taking part is that the check-ups in the hospital may take a little longer (possibly 10 minutes longer).

7. What happens after the study?
Will you receive the results of the study?
About 12 months after your child's participation, the researcher will inform you of the main results of the study. If you do not wish to know this, please tell the researcher. He will then not tell you.

8. What do we do with your data?
If your child takes part in the study, you also give permission for us to collect, use and store your child's data.

Which data do we store?
We store the following data:

A. your child's name

B. your child's sex

C. your child's email address

D. your child's date of birth

E. information about your child's health

F. your child's answers on the completed questionnaires

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

How do we protect your privacy?
To protect your privacy, we assign a code to your data. We place only this code on all of your data. We keep the key to the code 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, no one will be able to trace that the data belonged to your child.

Who can see your data?
Some people may see your child's name and other personal data without the code. These are people who check whether the researchers are carrying out the study properly and reliably. These persons may have access to your child's 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 people will keep your data confidential. We ask for your permission for this access.

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

Can you withdraw your consent for the use of your data?
You may withdraw your consent for the use of your child's data at any time. Please note: if you withdraw your 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?
• If you would like to know more about your rights regarding the processing of personal data, please visit www.autoriteitpersoonsgegevens.nl.
• If you have questions about your rights, or a complaint about the processing of your personal data, please 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 recommend that you first discuss them with the research team. You may also contact the Data Protection Officer of OLVG or submit a complaint to the Dutch Data Protection Authority.

9. Will you receive compensation if your child takes part in the study?
Participation in the study will not cost you anything. You will not receive any compensation if your child takes part in this study. Travel costs for returning to the hospital will also not be reimbursed, because these check-up visits are necessary even without participation in the study.

10. Is your child insured during the study?
Your child is not additionally insured for this study, because participation in the study does not involve extra risks. Therefore, OLVG does not need to arrange additional insurance.

11. Do you have any questions?
If you have questions about the study, you can ask dr. Langeveld. Do you have a complaint? Please discuss this with the researcher or the doctor treating your child. If you would prefer not to, you can contact the complaints officer of OLVG. Appendix A tells you how to reach them.

12. How do you give consent for the study?
You may first take time to think about this study. After that, you tell the researcher whether you understand the information and whether you do or do not want your child to take part. If you want your child to take part, you complete the consent form. Both you and the researcher will receive a signed copy of this consent form.

Appendix A: OLVG contact details

Outcomes after nail luxations

Researcher:
M. Brouwer, MD
Email address: M.Brouwer2@olvg.nl

What to do in case of complaints?

If you have any complaints about the study, you can report them to the researcher. If you would rather not do this, you may contact the complaints officer of OLVG.

The complaints officer can be reached:

By telephone at location East: 020 599 22 93

By telephone at location West: 020 510 83 48

By email: klachten@olvg.nl

By letter to the postal address:

OLVG, attn. complaints officer

P.O. Box 95500

1090 HM Amsterdam

If you have questions or complaints about the processing of your personal data, we recommend that you first contact the research location. You may also contact the Data Protection Officer of OLVG or the Dutch Data Protection Authority (www.autoriteitpersoonsgegevens.nl).

The Data Protection Officer of OLVG can be reached:

By email: fg@olvg.nl

By telephone: 020 599 3875

For PIFs in English:

What to do in case of complaints?

In case you have any complaints about this study you can report this to the investigator or other study staff. If you would rather contact someone independent of the study, you can contact the complaints officer of OLVG.

Contact details of the complaints officer:

By telephone at location East: 020 599 2293

By telephone at location West: 020 510 8348

By email: klachten@olvg.nl

By post:

OLVG, attn. complaints officer

P.O. Box 95500

1090 HM Amsterdam

If you have complaints about the processing of your personal data, we advise you to first contact the research location. You can also contact the Data Protection Officer of OLVG or the Dutch Data Protection Authority (www.autoriteitpersoonsgegevens.nl).

Contact details of the data protection officer:

By email: fg@olvg.nl

By telephone: 020 599 3875

Appendix B Consent form participant (child)

Have this form signed by the patient and keep it in the Emergency Department!

- I have understood the information. I was also able to ask questions. My questions have been answered.
- I had enough time to decide whether I want to take part.
- I know that I am not obliged to take part.
- I understand that I may always stop if I no longer want to take part.
- I may be approached to take part in research in the future
- I want to take part in this study.

Patient

My name is (participant): ……

Signature: ……. Date : __ / __ / __

Healthcare professional

Additional information was provided by:

Name: ……

Position: ……

Signature: ……. Date: __ / __ / __

Researcher (M. Brouwer)

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

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

Name of researcher (or representative): ……

Signature: ……. Date: __ / __ / __

Appendix C: Consent form for the representative

Have this form signed by the representative and keep it in the Emergency Department!

- I have been asked to give permission for this person to take part in this medical scientific study:
- I have read the information letter for the participant/representative. I was also able to ask questions. My questions were answered well enough. I had enough time to decide whether I want this person to take part.
- I know that participation is voluntary. I also know that I can decide at any time that this person will no longer take part. I do not have to explain why.
- 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 understand that for monitoring the study, some people may have 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 that purpose.
- I agree that this person will take part in this study.

Patient

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

Representative (parent)

Name of legal representative: ……

Relationship to the participant: ……

Signature: …… Date: __ / __ / __

Healthcare professional

Additional information was provided by:

Name: ……

Position: ……

Signature: …… Date: __ / __ / __

Researcher (M. Brouwer)

I declare that I have fully informed the person(s) named above about the study. If information becomes available during the study that could affect the representative's consent, I will inform him/her in time.

Name of researcher (or representative): ……

Signature: …… Date: __ / __ / _