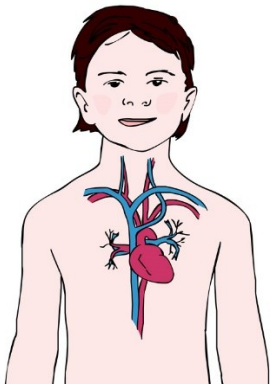
Information about the study for children under 12 years of age

Have the last page signed by the patient/representative and keep it in the Emergency Department!

What is this about?

We would like to ask you to take part in a study about your nail. We want to find out whether putting the nail back in place is useful or not.

You may decide for yourself whether you want to take part.



What will happen?

You have hurt your finger and your nail has come loose. The doctor can choose:

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.

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

When and how long?

· You will receive treatment straight away in the Emergency Department (with or without replacing the nail).

· 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. The doctor will ask questions about your finger. These questions are about what your fingertip looks like, how well you can use your finger, and about pain. These check-ups are part of standard care and are not only needed because you take part in the study.

· A visit is usually short, about fifteen minutes.

What are the advantages and disadvantages?

· Advantages:

- You may not need a painful treatment or injections if we do not put the nail back.

· Disadvantages:

- You need to come back to the hospital a few times.
- Your finger may remain sensitive while it is healing, but this can happen with both treatments.

Important to know:

- Taking part is not compulsory
- You can always stop without having to say why
- You can always ask questions.

If you have questions

You can discuss questions with your parents. Or you can ask them together with the researcher.

You can email the researcher at: M.Brouwer2@olvg.nl

Write your questions here:

Your decision

The form

If you want to take part, we need a signature from both of your parents/guardians (Appendix B)

You can also choose whether we may ask you later about another study. We will then give you information about that 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:

- your child's name
- your child's sex
- your child's email address
- your child's date of birth
- information about your child's health
- 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

Appendix B: 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

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: __ / __ / _