Information about a study for children under 12

Staff: have the parent(s)/guardian(s) sign the last page and put it in the black research mailbox (wetenschapsbrievenbus) at the short-care unit. Version 2.1, 16-11-2026.

What is it about?

We would like to ask you to take part in a study about wounds on the tip of your finger. We want to know whether a dressing without cream works just as well as the same dressing with a special cream underneath.

You can decide together with your parents/guardians whether you take part.

What will happen?

You have hurt your fingertip. There is still a small wound that needs to heal with a dressing. The doctor chooses which treatment suits your wound best:

- **The mesh dressing alone: a thin mesh that does not stick to the wound (Mepitel®) is placed on the wound, with a bandage around it.**
- **The mesh dressing with cream underneath: first a cream containing silver (Flammazine®) is put on the wound, and on top of it the same mesh with a bandage around it.**

The doctor chooses the treatment. There is no random allocation. After that we look at how quickly your wound heals.

When and for how long?

- You receive the treatment you need straight away in the Emergency Department.
- After that you come back to the Surgery outpatient clinic if the doctor thinks it is necessary. That is part of normal care.
- About 2 weeks after the accident you come back to the hospital for a check-up, as is usual after a wound like this. A doctor or nurse then looks at your wound, checks how much pain you have and takes a photo. In young children, pain can be assessed by watching the child closely. If your wound is closed, you do not need to come back. If your wound is not yet closed, you come back about a week later, until it is closed.
- Only your finger or hand may be in the photo. Your face, name or date of birth may not be in the photo. Your parents/guardians receive an e-mail twice with a few short questions about your finger and how you are doing.

What are the advantages and disadvantages?

You probably have no direct benefit from taking part yourself. By taking part you help doctors to know better which dressing works best for this kind of wound.

A disadvantage is that your parents/guardians answer a few short questions twice. Your finger may be sensitive while it heals. That can happen with both treatments.

Important to know

- Taking part is not compulsory.
- You can always stop.
- You can always ask questions.

If you have questions

You can discuss questions with your parents/guardians. Or you can ask the researcher together. You can e-mail the researcher at: M.Brouwer2@olvg.nl

Space to write down your questions:

_____

_____

_____

_____

_____

Your decision

Do you want to take part? Then we need a signature from your parents/guardians. This is in Appendix B.

Information for parents/guardians

Dear Sir/Madam,

With this information letter we would like to ask whether you want your child to take part in a medical research study. Taking part is voluntary. You are receiving this letter because your child has a wound on the fingertip caused by an accident, and after the initial treatment an open wound remains that needs dressing care.

Here you can read what the study is about, what taking part involves, and what the advantages and disadvantages are. Please read the information carefully and then decide whether you want to take part.

Ask your questions

You can make your decision based on the information in this letter. We also advise you to ask the researcher or your treating doctor any questions you have, and to discuss the information with your partner, family or friends. You can also find information at www.rijksoverheid.nl/mensenonderzoek (in Dutch).

1. General information

OLVG hospital has set up this study. Below we refer to OLVG as the sponsor. The study is carried out within OLVG. The committee that has reviewed the study is the Scientific Research Advisory Committee (Adviescommissie Wetenschappelijk Onderzoek, ACWO).

2. What is the purpose of the study?

The purpose of this study is to find out whether wound care with only a thin silicone mesh dressing that does not stick to the wound (Mepitel®) is no worse than wound care with a silver-containing cream (Flammazine®) applied underneath it, for open fingertip wounds caused by an accident. We mainly look at whether the wound is completely closed 3 weeks after the accident.

We also look at pain, infection, complications, satisfaction, the number of check-ups and any additional treatment. Pain is measured in an age-appropriate way: in children under 8 years with a short observation score (FLACC), and in children aged 8 years and older and adults with a 0-10 pain score.

3. What is the background of the study?

Open fingertip wounds are common after, for example, cutting, crushing or sawing injuries. Sometimes the nail or nail bed is also injured, there is a small fracture of the tip of the finger bone, or bone is exposed. The wound usually heals by itself with good dressing care.

In practice, doctors use different types of wound dressing. A thin mesh dressing that does not stick to the wound (usually Mepitel®) is always placed on the wound. Sometimes the doctor first applies Flammazine® underneath it: a cream containing silver sulfadiazine, usually for a maximum of one week. It is not certain whether this cream has any extra benefit for this type of wound. That is why we want to compare the outcomes of these two treatments: the mesh dressing alone, or the mesh dressing with the cream underneath.

The doctor chooses the treatment based on the normal medical assessment. There is no random allocation. The study does not change the acute treatment; we collect data on the treatment chosen and on the recovery afterwards.

4. How is the study carried out?

Treatment

In the Emergency Department the wound receives the treatment the doctor considers appropriate at that moment. This may include, for example, cleaning the wound, local anaesthesia, bandaging, treatment of any nail or bone injury if needed, and then wound care with a thin mesh dressing that does not stick to the wound (Mepitel®), with or without Flammazine® underneath.

Follow-up, photos and short questions

The medical check-ups take place at the Surgery outpatient clinic as part of normal care. About 14 days after the accident the usual wound check takes place. A healthcare professional then examines the wound, asks a few short questions about the wound and your pain, and takes a photo of the wound with a secure hospital app; the photo goes directly into your medical record. If the wound is closed, no further check-ups are needed. If the wound is not yet closed, another check-up with a photo follows about a week later (around day 21) as part of normal care, and then weekly if needed until the wound is closed. The photos help us to determine reliably whether the wound has healed and to record any problems properly. A photo of the wound is also taken in the Emergency Department directly after treatment.

In addition, you will receive an e-mail with a short digital questionnaire twice: about 12 days and about 19 days after the accident. The questions are about pain (children aged 8 years and older answer these themselves; for younger children you assess the pain yourself during a dressing change by watching your child closely), what your child can do with the hand and finger (you fill this in as parent/guardian) and how satisfied you are with the treatment. Completing it takes about 5 minutes. For this we use the e-mail address in your OLVG record. The e-mail comes from "Max Brouwer" and is sent via Castor, the secure research system that OLVG uses for this study (sender address no-reply@castoredc.com). The address of the link in the e-mail therefore contains the name Castor; we will never ask you for a password or bank details. If you are unsure whether the e-mail is genuine, please contact the researcher before opening the link. If you do not have an e-mail address, you will be given the questionnaire on paper or we will go through it with you by telephone. You do not need to take or send any photos yourself. The photos taken by the healthcare professional show only the affected finger or hand, without face, name or other identifiable personal details. The researcher will only contact you in between if a questionnaire has not been completed or if symptoms or possible complications are reported.

What is different from normal care?

The treatment and the check-ups at the Surgery outpatient clinic are part of normal care. The wound checks around day 14 and, if the wound is not yet closed, around day 21 are also part of normal care. The extra part for the study is that at those check-ups we ask for a short pain score and take the wound photo in a standardised way, and that you receive two short digital questionnaires by e-mail (around day 12 and day 19). Information about extra check-ups, antibiotic use and any additional treatment is taken from your medical record, up to 6 weeks after the accident. Taking part may therefore cost you a little extra time.

5. What do we agree with you?

- You follow the wound care instructions of your treating doctor.
- You attend the usual wound checks with your child around day 14 and, if the wound is not yet closed, around day 21; a wound photo is taken there.
- You contact the researcher if you no longer wish to take part.
- You let us know about any change in your telephone number or e-mail address, so that the questionnaires reach you.

6. What are the advantages and disadvantages if your child takes part?

Taking part probably has no direct medical benefit for you. By taking part, you help the researchers gain more insight into the best wound care for open fingertip injuries.

The disadvantages are that taking part costs some time, mainly because of the two short digital questionnaires (about 5 minutes each). The wound may be tender or painful while it heals. This can happen with both treatments. There are no extra medical risks from taking part in this observational study.

7. What happens after the study?

About 12 months after your participation, the researcher may let you know the main results of the study. If you would rather not know, please tell the researcher.

8. What do we do with your data?

If your child takes part in the study, you give permission for us to collect, use and store data.

Which data do we store?

- name, date of birth, sex and contact details of your child and/or parent/guardian, including the e-mail address for sending the questionnaires;
- medical data about the injury, the treatment, wound healing and check-ups;
- your answers to the digital questionnaires (pain, use of hand and finger, satisfaction) and data on complications and any additional treatment; depending on age, pain is recorded with FLACC or a 0-10 pain score;
- wound photos taken by the healthcare professional in the Emergency Department and at the check-ups, for assessment of wound healing.

Why do we collect, use and store these data?

We collect and use these data to answer the research questions and to be able to publish the results. In publications it will not be possible to identify whose data they are.

How do we protect your privacy?

The research data are coded. This means that the research data carry a study number instead of your name or other directly identifiable details. The key linking your name and study number is stored separately and securely within OLVG. Only authorised members of the research team have access.

Wound photos are stored in your medical record and, for the study, are stored coded under the study number in a secure OLVG study folder. The answers to the questionnaires are stored under the study

number in the secure research system Castor. The photos are not stored on private devices or in a personal mailbox.

Who can see your data?

Some people may see the data without the code in order to check whether the study is being carried out properly and reliably. These may be: members of the reviewing committee, a monitor working for OLVG, and national or international supervisory authorities. These people keep your data confidential.

How long do we keep your data?

The data are kept at OLVG for 10 years.

Can you withdraw your consent?

You can withdraw your consent at any time. Data that have already been collected before you stop may still be used for the study, unless you indicate that this is not allowed, insofar as the law permits.

Would you like to know more about your privacy?

More information about your rights regarding the processing of personal data can be found at www.autoriteitpersoonsgegevens.nl. If you have questions or complaints, you can contact the research team, the Data Protection Officer of OLVG or the Dutch Data Protection Authority (Autoriteit Persoonsgegevens).

9. Will you be reimbursed?

Taking part in the study costs nothing. There is no payment for taking part. Travel costs are not reimbursed, because the physical check-ups take place as part of regular care and are not scheduled additionally for the study.

10. Are you insured during the study?

Your child is not additionally insured for this study, because taking part involves no extra medical risks. OLVG therefore does not need to take out extra insurance.

11. Do you have any questions?

You can ask questions about the study to M. Brouwer, MD. Do you have a complaint? Please discuss it with the researcher or the doctor treating your child. If you would rather not, you can contact the complaints officer of OLVG. Appendix A explains how to reach them.

12. How do you give consent?

You can take your time to think about taking part. If you want your child to take part, please complete the consent form for parents/legal representatives. The signed form is kept by OLVG; you keep this information letter yourself. If you would like a copy of the signed consent, you can request it from the researcher.

Thank you for your time.

Appendices:

- Appendix A: OLVG contact details
- Appendix B: consent form legal representative

Appendix A: OLVG contact details

TOP 4 study: wound care for traumatic fingertip injuries

Researcher:

M. Brouwer, MD

E-mail: M.Brouwer2@olvg.nl

What to do if you have a complaint?

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

The complaints officer can be reached:

- By telephone, location Oost: 020 599 22 93
- By telephone, location West: 020 510 83 48
- By e-mail: klachten@olvg.nl
- By post: OLVG, attn. complaints officer (klachtenfunctionaris), P.O. Box 95500, 1090 HM Amsterdam

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

Data Protection Officer OLVG:

- By e-mail: fg@olvg.nl
- By telephone: 020 599 3875

Appendix B: Consent form legal representative

Staff: have the legal representative(s) sign this form and put it in the black research mailbox at the short-care unit.

TOP 4 study: wound care for traumatic fingertip injuries

- I have been asked to give consent for this person to take part in this medical research study.
- I have read the information letter for the participant/legal representative. I was also able to ask questions. My questions have been answered sufficiently. I had enough time to decide whether I want this person to take part.
- I know that taking part 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 say why.
- I give the researchers permission to collect, use and store this person's data, wound photos and answers to the digital questionnaires. The researchers do this only to answer the research question.
- I know that some people may have access to this person's data in order to check the study. These people are named in the information letter. I give these people permission to see the data for this check.
- I agree to this person taking part in this study.

Patient

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

Legal representative 1

Name of legal representative: _____

Relationship to the participant: _____

Signature: _____ Date: __ / __ / __

Legal representative 2 (if applicable)

Name of legal representative: _____

Relationship to the participant: _____

Signature: _____ Date: __ / __ / __

Healthcare professional

Additional information was given by:

Name: _____ Position: _____

Signature: _____ Date: __ / __ / __

Researcher (M. Brouwer, or representative)

I declare that the person(s) above have been fully informed about the above study by me or by the healthcare professional named above. If information becomes known during the study that could influence the consent, I will inform them in good time.

Name of researcher (or representative): _____

Signature: _____ Date: __ / __ / __