

NINJA PARENT/GUARDIAN INFORMATION SHEET

Information for the Grown Ups!

Nail bed INJury Analysis (NINJA)

Should the nail plate be replaced or discarded after nail bed repair in children?

We would like to invite your child to take part in our research study.

Before you decide if your child can take part, we would like you to understand why the research is being done and what it would involve for you and your child.

Please take time to read the following information and discuss it with others if you wish.

Does my child have to take part?

Your child's participation in this study is entirely voluntary and you are free to withdraw them at any time, without giving any reason. Not taking part will not affect their care in the hospital.

The first part of this leaflet tells you the purpose of the study and what will happen if your child takes part.

The second section provides more detailed information about how the study will be performed.

Thank you for taking the time to consider this study.

Summary – a few important things you need to know:

1. This study is looking at children who are having surgery for a nail bed injury.
2. They will need this operation whether they are part of the study or not.
3. Children who participate in the study will be randomly allocated to one of two groups – nail replaced or nail discarded.
4. We are assessing whether replacing the finger nail after nail bed surgery is better than not replacing it.
5. We would like to look at the rates of infection and the appearance of the fingernail.
6. We will collect information about children's injury and the operation.
7. At your child's standard clinical appointment 7-10 days after the operation we will assess how your child is doing and ask some questions about the fingernail and your child's health. We will also ask you to complete a short questionnaire.
8. We will ask you to complete a similar short questionnaire after 4 months – this will be sent to you via email or post – whichever you prefer.
9. At 4 months we will also ask you to send us a photo of your child's fingernail so we can see how it looks at that time.
10. This study is recruiting over 400 patients from around 25 hospitals around the UK.

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The Facts and the Questions

Nail bed injury information

- A nail bed injury affects the soft tissue underneath the nail as well as the nail itself.
- It is often caused by a child jamming their finger in a door or getting their finger stuck in an object.
- It requires surgery to repair the injury underneath the fingernail.
- To do this, the fingernail needs to be removed – it is often broken or partially detached already.
- Surgeons repair the injury with tiny dissolving sutures.
- This is to help the new nail to grow out smoothly and look as normal as possible in the future.
- The finger is bandaged at the end and the patient can normally go home the same day.
- You and your child will be asked back to the clinic in about a week to see how the nail bed is healing.
- It usually takes about 4 months for a new nail to grow out from the base.

NINJA-P

In 2015 we did a smaller version of this study. This is called a “pilot study”. We called it NINJA-P. We recruited 60 patients from 4 hospitals. We did this to see if this larger study was possible. The information we collected in the pilot study has helped us design this study.

Why does there need to be a study?

- Traditionally the nail was replaced after the nail bed is repaired.
- Recently surgeons are thinking that replacing the fingernail may not be essential.
- Both of these techniques (replacing the nail and discarding the nail) are routinely done in the NHS.

However, we don’t know which is best – so we are doing a study to compare whether replacing the finger nail is better than not replacing it!

The treatment options are shown below:

1. Replace the old nail before applying dressings



The nail has been replaced after repairing the nail bed and held in place by a “figure-of-8” stitch. Dressings are then applied.

2. Discard the nail and apply dressings straight onto the nail bed.



The nail has been discarded. The nail bed repair, with multiple tiny stitches, is visible. Dressings are then applied

We’ve asked you and your child to participate because they have a nail bed injury that requires an operation to fix it.

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What would taking part involve?

At the start

- We talk to parents/guardians and their child about the study, give the child age-appropriate information about the study to help them understand, answer any questions you may have, and if acceptable take written consent from you and assent from the child if they would like.
- We would ask you to complete some short questionnaires (5 min) about your child, their general health, and the injury and allow us to collect information about their operation.



At the 7-10 day check-up

During your child's standard clinic visit:

- A doctor or nurse will change the finger dressings
- They will assess your child's fingertip for any signs of infection.
- If an infection is identified they will treat it appropriately, usually with a course of antibiotics.



As part of the NINJA study:

- We will ask you and your child (if appropriate) to complete some questionnaires about the child's general health, how the fingernail has been healing and any health care you've accessed for the fingernail.
- Some of the questionnaire will be completed in the clinic and some will be sent to you via email or post (whichever you prefer) so you can complete this in your own time.
- The questionnaires should take about 15-20 minutes to complete.
- We will provide a postal envelope to return paper questionnaires.



4 months after the operation

- We will send you some similar questionnaires via post or email again
- The questions will be similar to the ones asked in the clinic visit and take 15-20 minutes to complete.
- We will provide a postal envelope to return paper questionnaires.
- You will also be asked to take a photo of your child's injured finger and the same finger on the other hand, side by side, then send this in via a secure web link.
- We will send you a template and full instructions on how to do this. The photos will allow us to assess how the new fingernail has grown out and how the finger looks in comparison to the others.
- The photo should look something like this:



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How will the treatment option be decided?

All patients will require surgery to repair their fingernail injury as part of their clinical care. If they participate in the study, whether the fingernail is replaced or discarded will be decided by a process called *randomisation*

Randomisation (like tossing a coin) means whether your child has their finger nail replaced or discarded is decided randomly. This is done via a computer programme.

We are doing this because it is the best way to allow a fair comparison to be made between the 2 treatment options. Dividing people into groups in this way is what is called a “randomised clinical trial” and it is the standard and only reliable way to see how good a treatment is.

Please note – your child will still receive the same care before, during and after their operation regardless of whether their fingernail is replaced or discarded.

The NINJA Community

1. The Important Information:

- The NINJA Facebook group is a secure group specifically set up for the NINJA participants and their grown-ups.
- It is administered and managed by the NINJA team at the University of Oxford.
- It is not accessible to the public.
- NINJA grown-ups will be invited to join by the study team in Oxford – it is not compulsory.
- NINJA participants will only be able to join if they already have their own Facebook account.
- All postings will be subject to review by the central NINJA study team before approval is granted.

2. The Fun Information:

- The Facebook group will have competitions for the NINJA participants such as:
 - NINJA drawing competitions
 - Word jumbles & crosswords
 - Photo diaries
 - Finger trivia

We have also consulted with patients and parents from regarding the best way to do this study. Their information has been hugely beneficial. You can see more information about how parents and children have helped us design our study at www.ninja.octru.ox.ac.uk.

What are the possible benefits of taking part?

We cannot guarantee that your child will get any direct benefit from taking part in this trial. However, your child taking part will help us to answer our question, which may lead to better care and outcomes after surgery in patients with nail bed injuries in the future.

What are the possible disadvantages of taking part?

The surgery that your child will receive is the same whether they take part in the study or not. You will be asked to complete some short questionnaires (15-20 mins) and submit a photograph in addition to any clinical treatment you receive.

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What happens when the research study finishes?

The results of this study will tell us if way we manage nail bed injuries in children can be done better in the future. Participants will be identified only by a participant ID number on all trial documents and in any electronic database. Data will be anonymous when analysed and published in per-reviewed journals

What if there is a problem during the study?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that your child should suffer any harm arising from the negligence of the University, or that of a collaborator in this research, and with that harm resulting as a direct consequence of their participation in this trial.

Taking part in this study will not affect your child’s legal rights. If at any point you are unhappy with the research or wish to complain about any aspect of the way in which you or your child have been approached or treated during the course of this study please contact your local clinical care team.

<name of investigator>

<contact details (phone number & email)>

Or

<name of investigator>

<contact details (phone number & email)>

You may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG by email at ctrg@admin.ox.ac.uk

The central NINJA study team in Oxford

NINJA Study Team, Surgical Intervention Trials Unit (SITU), Botnar Research Centre
Windmill Road, Headington, Oxford, OX3 7LD
Email: ninja@ndorms.ox.ac.uk Tel: 01865 227715

Will taking part in this study be kept confidential?

Yes. All patient information will be stored on password protected computer databases or in locked filing cabinets. Your child will be allocated a study number and staff not directly involved with you and your child will know you and your child only by this number. When the results of the study are reported, individuals who have taken part will not be identified in any way.

Patient details will be forwarded to the central study office based in Oxford. These will be securely stored and used to coordinate the email/postal follow up and other study processes as appropriate.

Responsible members of the University of Oxford or your NHS Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with research regulations. All the data will be archived centrally and destroyed after 5 years.

What will happen if I don't want to carry on with the study?

Participation is voluntary and if you or your child decide to withdraw from the study, you may do so at any time, you do not need to give a reason. Withdrawal will not affect your child’s care in the hospital. Any data collected from your child up to the point of withdrawal may be used for the study, unless you tell us otherwise.

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Will I find out the results of the study?

We plan to publish the results in a medical journal so that others can read about and learn from the results of the study. There will be no identifiable data of any children who take part in the results. Participants and their families will also be sent a summary of the study with details on where to find further information.

Who is organising and funding this research?

The research idea originated from a group of surgeons who have worked with the Surgical Intervention Trials Unit (SITU) in Oxford. They have designed and will manage the research. The SITU team includes researchers, nurses, statisticians, methodologists and others who have experience running surgical trials.

The study is funded by a grant from the National Institute of Health Research (NIHR) Research for Patient Benefit (RfPB) Programme. NINJA is supported by the following communities:

- British Society for Surgery of the Hand (BSSH) - which is the information and education body for Hand Surgery in the UK and they funded the pilot study we ran in 2015.
- British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) – a plastic surgery forum.
- Reconstructive Surgery Trials Network (RSTN) - is the clinical trials network for plastic surgery and hand surgery in the UK. It is part of the RCS Clinical Trials Initiative and many of the surgeons involved in NINJA belong to the RSTN.

Expenses

Reasonable travel expenses for any visits **additional** to normal care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given a favourable ethical opinion for conduct in the NHS by South Central Berkshire B Research Ethics Committee. It has also been approved by the Research Department at this hospital.

Who is the NINJA trial contact at our hospital?

<NAME>
<ADDRESS>

<TELEPHONE>
<EMAIL>

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