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Nail bed INJury Analysis (NINJA)

Submission date
23/04/2018

Recruitment status
No longer recruiting

Registration date
24/04/2018

Overall study status
Completed

Last Edited
27/11/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nail bed injuries are the most common hand injury in children in the UK. Treatment usually involves surgical repair of a laceration located underneath the fingernail. To do this the fingernail is removed, the laceration repaired, and the fingernail can be replaced or discarded. Historically the nail was replaced routinely but recent evidence indicates not replacing the nail may reduce the incidence of infection and complications after surgery. The aim of this study is to compare replacing the nail to the alternative practice of discarding (not replacing) the nail as part of the surgical nail bed repair for the treatment of nail bed injuries.

Who can participate?
Patients aged under 16 years with a nail bed injury

What does the study involve?
Participants are randomly allocated to have their nail plate replaced or discarded. The cosmetic appearance of the fingernail is assessed at the final follow-up (a minimum of four months up to 12 months) and the incidence of infection is assessed after 4 months.

What are the possible benefits and risks of participating?
It cannot be guaranteed that a child will get any direct benefit from taking part in this study. However, participating may lead to better care and outcomes after surgery in patients with nail bed injuries in the future. The surgery that a child will receive is the same whether they take part in the study or not. Parents/guardians will be asked to complete some short questionnaires (15-20 minutes) and submit a photograph in addition to any clinical treatment their child receives.

Where is the study run from?
Evelina London Children's Hospital (UK) and 19 other sites in the UK.

When is the study starting and how long is it expected to run for?
August 2018 to April 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
SITU-NDORMS team
situ@ndorms.ox.ac.uk

Study website
https://ninja.octru.ox.ac.uk/

Contact information

Type(s)
Scientific

Contact name
Dr SITU-NDORMS Team

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
219560

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 35666

Study information

Scientific Title
Nail bed INJury Analysis (NINJA): Should the nail plate be replaced or discarded after nail bed repair in children?

Acronym

NINJA

Study objectives
Nail bed injuries are the most common hand injury in children in the UK. Treatment usually involves surgical repair of a laceration located underneath the fingernail. To do this the fingernail is removed, the laceration repaired, and the fingernail can be replaced or discarded. Historically the nail was replaced routinely but recent evidence indicates not replacing the nail may reduce the incidence of infection and post operative complications. The NINJA trial is a multicentre, parallel group, randomised controlled trial comparing replacing the nail to the alternative practice of discarding (not-replacing) the nail as part of the surgical nail bed repair for the treatment of nail bed injuries. This study will be undertaken at multiple UK sites, identified through the Reconstructive Surgery Trials Network (RSTN) over a 3 year period. Each patient will be followed up for 4 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central: Berkshire-B, 20/02/2018, ref: 18/SC/0024

Study design
Randomized; Both; Design type: Treatment, Surgery, Validation of outcome measures

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Nail bed injuries

Interventions
Participants will be assigned to nail-plate replaced or nail-plate discarded groups. A web-based randomisation system will be used and the allocations will be computer generated with a 1:1 ratio, and stratified by site using random permuted blocks of varying size within stratum.

Despite their frequency, controversy remains around the appropriate treatment of nail bed injuries. Without proper treatment, injury to the nail complex has the potential to cause considerable dysfunction and/or deformity. The long-accepted teaching has been to remove the nail plate (i.e. the fingernail), repair the underlying nail bed laceration with fine absorbable

sutures and replace the nail under the eponychium (i.e. nail fold). The replaced nail has no capacity for re-growth. Instead, as a new nail begins to grow, the replaced nail is gradually pushed out until it becomes loose. The rationale for replacing the nail is that it both protects the nail bed repair and acts as a 'splint' by holding open the nail fold and preventing scarring between the nail fold and the nail bed (synechiae). However, there is no evidence that replacing the nail has better results than not replacing it. The Nail bed INJury Assessment (NINJA) trial seeks to answer the question "should the nail plate be replaced or discarded after nail bed repair in children, as evaluated by overall complications and appearance of the nail?

Participants will be followed up for a total of 4 months after randomisation.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure:
1. The cosmetic appearance of the fingernail as defined by the Oxford fingernail appearance score (OFNAS) at final follow-up (a minimum of four months up to 12 months post-randomisation)
2. The incidence of infection defined as per the centres for disease control criteria (CDC 1993) within 4 months

Previous primary outcome measure:
1. The cosmetic appearance of the fingernail as defined by the modified Zook score at 4 months
2. The incidence of infection defined as per the centres for disease control criteria (CDC 1993) within 4 months

Secondary outcome measures
1. Health-related quality of life, measured by EuroQol EQ-5D-(Y), EuroQol EQ-5D-(Y) proxy and PedsQL completed by the child or parent/guardian according to the age of the participant at 7-10 days and 4 months
2. Level of pain experienced by the child at their first dressing change according to the child or judged by the parent/guardian (3 point Likert scale for children [modified Wong Baker scale]) at 7-10 days and 4 months
3. The cost effectiveness (including resource use) measured by healthcare resource utilisation reports from the parent/guardian (i.e. hospital visits, dressing and antibiotic use and in some cases hospital readmission and repeat surgery), measured at 7-10 days and 4 months
4. Chronic infection within the last 4 months, measured by participant reported incidence of infection with clinical notes confirmation at 7-10 days and 4 months
5. Participant or parent/guardian reported satisfaction with nail healing, measured by 3 point Likert scale for the children (if old enough) and a VAS score for the parents/guardians at 4 months

Overall study start date
01/09/2017

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Male or female, aged below 16 years old at the time of presentation to the participating unit
2. Acute nail bed injury (occurring within 48 hours of presentation at trial centre) believed to require surgical repair by the admitting surgical team. This includes sharp lacerations, stellate lacerations, crush and avulsion injuries of the nail bed, injuries involving the sterile and/or germinal matrix, nail bed injuries with an associated pulp laceration and/or with an associated 'tuft' fracture of the distal phalanx
3. Patients whose parent or legal guardian consent to their inclusion in the trial and are willing to return for follow up (including submission of photos)
4. Sufficient understanding of the child and parent/guardian participant information sheets as deemed by recruiting team at local sites
5. Single digit nail bed injury

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 416; UK Sample Size: 416

Total final enrolment
451

Key exclusion criteria
1. Patients who present with an already infected nail bed injury
2. Patients with underlying nail disease or deformity in the injured or contralateral finger prior to the injury
3. Patients with an associated distal phalanx fracture requiring fixation with a Kirschner wire
4. Patients with complete amputation of the distal fingertip including all or part of the nail bed
5. Patients with loss of part or all of the nail bed, requiring a nail bed graft or flap reconstruction
6. Previous NINJA trial participant (assessed at baseline)
7. Multiple nail bed injuries

Date of first enrolment
06/07/2018

Date of final enrolment
01/07/2019

Locations

Countries of recruitment

England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Evelina London Children's Hospital (lead centre)
Westminster Bridge Road
Lambeth
London
United Kingdom
SE1 7EH

Study participating centre
Broomfield Hospital
Court Road
Broomfield
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre

Chelsea and Westminster Hospital
369 Fulham Rd
Chelsea
London
United Kingdom
SW10 9NH

Study participating centre
Leeds General Infirmary
Great George St
Leeds
United Kingdom
LS1 3EX

Study participating centre
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Queen Victoria Hospital
Holtye Rd
East Grinstead
United Kingdom
RH19 3DZ

Study participating centre
Royal Cornwall Hospital
Truro
United Kingdom
TR1 3LQ

Study participating centre
Royal Derby Hospital
Derby
United Kingdom
DE22 3NE

Study participating centre
Royal Hospital for Sick Children
9 Sciennes Road
Edinburgh
United Kingdom
EH9 1LF

Study participating centre
Royal Manchester Children’s Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Salisbury District Hospital
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
St George's Hospital
Blackshaw Rd
London
United Kingdom
SW17 0QT

Study participating centre
Stoke Mandeville Hospital
Mandeville Road

Aylesbury
United Kingdom
HP21 8AL

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
The Ulster Hospital
Upper Newtownards Road
Dundonald
Belfast
United Kingdom
BT16 1RH

Study participating centre
University Hospital of Wales
Heath Park Way
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CF14 4XW

Study participating centre
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SL2 4HL

Sponsor information

Organisation
University of Oxford

Sponsor details

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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1215-20041

Results and Publications

Publication and dissemination plan
Protocol will be available once published, other documents will be available on request. Planned publication of the study results in a high-impact peer reviewed journal in 2021.

Intention to publish date
01/04/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/12/2019	22/10/2020	Yes	No
Statistical Analysis Plan		07/10/2020	31/10/2022	No	No
Results article		22/03/2023	23/03/2023	Yes	No
HRA research summary			28/06/2023	No	No

Results article	cost-effectiveness	11/08/2023	08/07/2024	Yes	No