ISRCTN16571591 https://doi.org/10.1186/ISRCTN16571591

Nail bed INJury Analysis (NINJA-P)

Submission date
20/05/2015

Recruitment status
No longer recruiting

Registration date
21/05/2015

Overall study status
Completed

Last Edited
21/11/2018

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Accidental injuries to fingernails and the nail bed underneath are very common, especially among children. Injuries can arise as a result of various factors, such as having the fingers crushed while playing, or getting them caught in a closing door. Sometimes, surgery is required to repair the damage and reduce pain in the injured fingernail. Surgery can also reduce the likelihood of future nail deformity and risk of infection. Standard treatment for nail bed injuries involves removal of the damaged fingernail (which may already be partially detached) and repair of the nail bed using dissolvable stitches. Following this treatment, the surgeon can either replace the old nail before applying the dressings, or discard the nail and apply dressings straight onto the nail bed. Both techniques encourage the new nail to grow as normally as possible, but it is not known if one of these techniques works better than the other. This study seeks to answer the question: should the nail be replaced or discarded after nail bed repair in children? This study also aims to assess how feasible it would be to carry out a larger study within the NHS.

Who can participate?
Children under 16 with nail bed injury acquired within the previous 48 hours.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) have their nail replaced following treatment to repair the nail bed. Those in group 2 (intervention group) have their nail discarded following treatment to repair the nail bed. Follow up assessments are carried out to determine post-operative complications, appearance of the nail and patient pain levels.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
April 2015 to September 2015

Who is funding the study?
British Society for Surgery of the Hand (UK)

Who is the main contact?
Miss N Farrar

Contact information

Type(s)
Scientific

Contact name
Miss Nicola Farrar

Contact details
University of Oxford
Nuffield Orthopaedic Centre
Windmill Road
Oxford
United Kingdom
OX3 7LD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18516

Study information

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

Acronym
NINJA-P

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ref: 15/LO/0067

Study design
Randomised interventional study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Injury to the nail bed in children which requires surgery

Interventions
Replace or discard nail plate after nail bed injury.

Intervention Type
Procedure/Surgery

Primary outcome measure
Complications measured at 2 weeks, 30 days and 4 months post intervention

Secondary outcome measures
1. Pain at dressing change measured at 2 week dressing change - before and during dressing change
2. Visual Analogue Score used 4 months post intervention
3. ZOOK classification measured at 4 months

Overall study start date
21/04/2015

Completion date
15/09/2015

Eligibility

Key inclusion criteria
1. Age <16 years
2. Acute nail bed injury (occurring within 48 hours of presentation at trial centre) requiring surgical repair. 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

Participant type(s)
Patient

Age group
Child

Upper age limit
16 Years

Sex
Both

Target number of participants
UK Sample Size: 60

Key exclusion criteria
1. Patients aged >16 years
2. Patients who present with an already infected nail bed injury
3. Patients with underlying nail disease or deformity prior to the injury
4. Patients with an associated distal phalanx fracture requiring fixation with a Kirschner wire. This is considered to be another potential source of infection and therefore a confounding variable
5. Patients with complete amputation of the distal fingertip including all or part of the nail bed, which requires repair as a composite graft or replantation
6. Patients with loss of part or all of the nail bed requiring a nail bed graft or flap reconstruction

Date of first enrolment
21/04/2015

Date of final enrolment
15/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Nuffield Orthopaedic Centre
Windmill Road
Oxford

United Kingdom
OX3 7LD

Sponsor information

Organisation
University of Oxford

Sponsor details
Old Road
Headington
Oxford
England
United Kingdom
OX3 7LF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
British Society for Surgery of the Hand (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	19/08/2015		Yes	No
Results article	results	01/11/2017		Yes	No
HRA research summary			28/06/2023	No	No