

# NINJA

## Nail bed INJury Analysis

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| <b>Study Title</b>          | Nail bed INJury Analysis (NINJA): Should the nail plate be replaced or discarded after nail bed repair in children?   |  |
| <b>Short title</b>          | NINJA   |  |
| <b>Study Design</b>         | Pragmatic multicentre randomised controlled study   |  |
| <b>Study Participants</b>   | Children under 16 with nail bed injuries requiring surgery  |  |
| <b>Planned Sample Size</b>  | 416   |  |
| <b>Planned Study Period</b> | 3 years   |  |
|                             | <b>Objectives</b>   | <b>Outcome Measures</b>  |
| <b>Primary</b>              | To assess the effects of replacing or discarding the fingernail by comparing the risk of infection and cosmetic appearance.   | <ul style="list-style-type: none"> <li>Confirmed incidence of infection (clinical assessment at 7-10 days and participant or parent/guardian reported with clinical notes at 4 months).</li> <li>Modified Zook Score assessing nail appearance at 4 months, considering 5 domains (shape, adherence, eponychium, surface quality and presence of split).</li> </ul>  |
| <b>Secondary</b>            | <ul style="list-style-type: none"> <li>To assess whether there is a difference in participant or parent/guardian reported health-related quality of life at 7-10 days and 4 months according to whether the nail is replaced or discarded.</li> <li>To assess whether there is a difference in participant or parent/guardian -reported pain experienced at 7-10 days and 4 months between replacing or discarding the nail.</li> <li>To conduct a parallel within-trial economic analysis to assess the cost effectiveness (including resource use) of replacing versus discarding the nail at 7-10 days and 4 months.</li> <li>To assess if any chronic infection has occurred within the last 4 months.</li> <li>To assess participant or parent/guardian reported satisfaction with nail healing</li> </ul> | <ul style="list-style-type: none"> <li>EuroQol EQ-5D-(Y), EuroQol EQ-5D-(Y) proxy and PedsQL, (baseline, 7-10 days and 4 months) completed by the child or parent/guardian according to the age of the participant</li> <li>The level of pain experienced by the child at their first dressing change according to the child or judged by the parent/guardian (7-10 days) (3 point Likert scale for children [modified Wong Baker scale])</li> <li>Healthcare resource utilisation (7-10 days and 4 months) such as increased hospital visits, dressing and antibiotic use and in some cases hospital readmission and repeat surgery</li> <li>Participant reported incidence of infection with clinical notes confirmation</li> <li>Child or parent/guardian satisfaction with nail healing (3 point Likert scale for the children (if old enough) and a VAS score for the parents/guardians at 4 months)</li> </ul> |