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POINT: A trial of surgery versus splinting for the treatment of proximal phalanx shaft finger fractures in adults

Submission date
17/01/2020

Recruitment status
No longer recruiting

Registration date
20/01/2020

Overall study status
Completed

Last Edited
08/08/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study investigates the treatment of a common type of bone break in the section of the finger closest to the knuckle. This injury is called a proximal phalanx shaft finger (PPS) fracture. PPS fractures result from falls, twisting forces or blows to the hand. They are treated in hospital by hand specialists which involves multiple visits to hospital and recovery takes several weeks to months, during which use of the hand is restricted. The aims of treatment are bone healing in good position, prevention of stiffness and return to full function. Although many people heal well, some fractures cause permanent pain, finger stiffness or deformity, which limit use of the hand and affect the way the finger looks. Serious problems need further treatment, including complex surgery. AIM PPS fractures can be treated with or without surgery and we don't know which is best. Current treatment is based on what each specialist believes works best and can vary. NHS hand specialists, patients with PPS fractures and researchers worked together to plan this study, so that a fair and useful comparison of treatments can be made. We will compare two treatments: surgery using metalwork (pins, screws or plates) to fix the fracture versus treatment using finger splints applied in clinic, but sometimes requiring local anaesthetic to improve the fracture position. The aim is to improve care by finding out which treatment is better for the patient; also which represents best value for money.

Patients and the public were involved in prioritizing the research question via the James Lind Alliance Priority Setting Partnership on Common Conditions of the Hand and Wrist. Patients with PPS fractures were actively involved in the study design via a national workshop with clinicians and researchers and two patient focus groups. We established a patient representative group to support our patient co-applicant, who has experienced a PPS fracture treated in the NHS. Two patient representatives will also help oversee the study.

Who can participate?
Adult patients with one or more proximal phalanx shaft finger fracture(s) suitable for surgical or non-surgical splint treatment.

What does the study involve?
Participants will be approached and recruited in secondary care fracture clinics. After giving informed consent to participate in the trial, participants will be randomly assigned to either receive surgery or non-surgical splint treatment. Any other treatment decisions (such as the type of surgery or splint, when to move the finger or take x-rays) will be made by the specialists and the patient, as is done in usual care outside the study.

Participants will be asked to complete questionnaires about how well they can use their hand and their general health (online or by post) at 6 weeks, 6 months and 12 months after joining the study. The primary outcome for the study will be a comparison of a patient completed questionnaire - Patient Evaluation Measure (PEM) at 6 months, compared to the start of the study.

Participants will also be asked to attend a trial clinic visit at 3 months where data will be collected and tests on hand function will be performed (range of motion, grip and pinch strength).

What are the possible benefits and risks of participating?
Possible benefits: You will receive the same level of care from your doctors, whether you choose to participate in the study or not. You may not benefit personally from taking part in this study, but because of the contact with the research team, you will have more regular or frequent opportunity to discuss your PPS finger fracture.

By taking part in this study you will also help to improve the treatment of future patients presenting with a PPS finger fracture. This means that people with such a fracture may in future experience a quicker or more convenient recovery, have fewer complications and better long-term use of their hand. The results of the study will also help plan effective services offered by the NHS.

Possible risks: Both treatments are a part of standard NHS care, so there is no extra risk involved in receiving them as part of the study. We do not know which of these treatments is best for patients with PPS finger fractures which is why we are doing this study. Taking part will mean spending some time to complete questionnaires and one extra visit to the hand clinic at hospital, three months after your first appointment.

Where is the study run from?
Nottingham Clinical Trials Unit, University of Nottingham (UK) and 13 Acute Care NHS Trusts (UK).

When is the study starting and how long is it expected to run for?
September 2019 to February 2024

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

Who is the main contact?
Ms Jennifer White, point@nottingham.ac.uk

Study website
https://www.nottingham.ac.uk/nctu/trials/musculoskeletal.aspx

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
277440

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 277440

Study information

Scientific Title
Surgery versus non-surgical splint treatment for proximal phalanx shaft fractures

Acronym
POINT

Study objectives
To determine the clinical and cost-effectiveness of surgery compared to non-surgical splint treatment for Proximal Phalanx Shaft (PPS) finger fractures in adults

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2020, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224558458; gram.nosres@nhs.scot), ref: 20/NS/0030

Study design
Pragmatic, multi-center, parallel, two-arm, superiority randomized trial

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Proximal phalanx shaft finger fractures

Interventions
Patients with a PPS fracture coming to hospital will be invited to take part in the study. Patients will then be treated in one of two groups: treatment with surgery OR non-surgical treatment using a finger splint. Each participant will have an equal chance of being in either group; neither the participant nor the specialist will be able to choose, this will be decided randomly by a computer. Any other treatment decisions (such as the type of surgery or splint, when to move the finger or take x-rays) will be made by the specialists and the patient, as is done in usual care

outside the study.
Participants will be asked to complete online or postal questionnaires at the start of the study, and at 6 weeks, 6 months and 12 months after joining the study.
Participants will also be asked to attend a trial clinic visit at 3 months where data will be collected and tests on hand function will be performed (range of motion, grip and pinch strength).

Intervention Type
Mixed

Primary outcome measure
Participant-reported assessment of hand function measured using the Hand Health Profile of the Patient Evaluation Measure (PEM) questionnaire at 6 months post-randomization

Secondary outcome measures
1. Participant reported assessment of hand function and appearance, using the Hand Health Profile of the PEM questionnaire at 6 weeks, 3 months, and 12 months.
2. Participant-reported assessment of location-specific health (the hand) using the Single Assessment Numeric Evaluation (SANE) tool at 6 weeks, 3 months, 6 months and 12 months.
3. Participant-reported quality of life assessment, using the EQ-5D-5L questionnaire, at 6 weeks, 3 months, 6 months and 12 months.
4. Participant-reported assessment of upper extremity function, using the Patient-Reported Outcomes Measurement Information System (PROMIS) computerised adaptive test, at 6 weeks, 3 months, 6 months and 12 months.
5. Participant-rated appearance of the hand as per item 10 of the Hand Health Profile of the PEM.
6. Investigator assessed active range of motion of affected digit(s), using a finger goniometer at 3 months.
7. Investigator assessed palmar grip and pinch strength of the affected hand, using a hydraulic dynamometer and pinch meter at 3 months.
8. Resource use and costs, assessed by a health economic analysis of health & social services costs (primary analysis) and effects on families and society (secondary analysis).
9. Participant and investigator reported complications, including need for further surgery, recorded in the Case Report Form and participant questionnaire responses.

Overall study start date
01/09/2019

Completion date
29/02/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 12/04/2022:
1. ≥1 Proximal Phalanx shaft finger fracture of any configuration
2. Aged ≥16 years
3. The fracture could be treated via either surgery or non-surgical splint treatment
4. Willing and able to give fully informed consent

Previous participant inclusion criteria:
1. Patients with one or more proximal phalanx shaft finger fracture(s)
2. Age ≥16 years
3. Fracture(s) suitable for either surgery or non-surgical splint treatment as assessed by the investigator
4. Willing and able to give fully informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
400

Total final enrolment
113

Key exclusion criteria
Current participant exclusion criteria as of 12/04/2022:
1. Injury >14 days old at the anticipated time of treatment
2. Pure Basal metaphyseal fracture
3. Pure Phalangeal neck fracture
4. Open fracture
5. Fracture pattern extending into the joint surface
6. Would not be able to adhere to trial procedures or complete the study questionnaires

Previous participant exclusion criteria:
1. Fracture(s) occurring ≥14 days before the anticipated time of treatment
2. Open fracture(s)
3. Basal metaphyseal fracture(s)
4. Phalangeal neck fracture(s)
5. Fracture patterns that extend into the joint surface
6. Inability to adhere to trial procedures or complete the study questionnaires

Date of first enrolment
01/04/2020

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Nottingham Clinical Trials Unit
University of Nottingham
Room A17
Building 42
University Park
Nottingham
United Kingdom
NG7 2RD

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Alexandra House
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
The Rotherham NHS Foundation Trust
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
University Hospitals Of Derby And Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
South Tyneside NHS Foundation Trust
South Tyneside District Hospital
Harton Lane
South Shields
United Kingdom
NE34 0PL

Study participating centre
St George’s University Hospitals NHS Foundation Trust
St George's Hospital

Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Buckinghamshire Healthcare NHS Trust
Amersham Hospital
Whielden Street
Amersham
United Kingdom
HP7 0JD

Study participating centre
University Hospitals Coventry And Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Chelsea And Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Cardiff & Vale University Local Health Board
Heath Park
Cardiff
United Kingdom
CF14 4XW

Sponsor information

Organisation

University of Nottingham

Sponsor details
Research and Innovation
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United Kingdom
NG8 1DH
01158467906
sponsor@nottingham.ac.uk

Sponsor type
University/education

Website
https://www.nottingham.ac.uk/fabs/research-innovation/home.aspx

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Research findings will be disseminated via a HTA monograph in the NIHR Journals library, scientific papers, conference presentations, and communicated to groups involved in guideline development and commissioning decisions.
Trial publications and conference presentations will be submitted to the NIHR HTA for approval prior to submission to the event organisers or the editors. All publications will acknowledge the support of the HTA in funding this trial. All participants will receive a copy of the trial results (unless they have stated they do not wish to receive this). Neutral or negative results will not constitute a reasonable justification to delay publication.

Intention to publish date
31/08/2024

Individual participant data (IPD) sharing plan
The datasets analysed during the current study will be available upon request from the NCTU (ctu@nottingham.ac.uk), a minimum of 6 months after publication of the main results paper. Access to the data will be subject to review of a data sharing and use request by a committee including the CI and sponsor, and will only be granted upon receipt of a data sharing and use agreement. Any data shared will be pseudoanonymised which may impact on the reproducibility of published analyses.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No