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FACTS: Surgical and non-surgical treatment for hand bone fractures in adults

Submission date
14/07/2020

Recruitment status
No longer recruiting

Registration date
14/07/2020

Overall study status
Completed

Last Edited
13/05/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Metacarpal shaft fractures are breaks (also known as fractures) in the middle part of the bones in the hand. They are very common injuries in young, working-age people. At the moment, we do not know how best to treat them, so patients get different care in different parts of the country. The best way of finding out is to do a trial comparing treatments. This study will assess whether a future trial is possible and how best to carry it out, to tell us the most effective way of treating these injuries.

Who can participate?
Adults (16 years and over) who have had a break in the middle part of the index to little finger metacarpal.

What does the study involve?
Participants will be asked to attend one clinic visit in addition to their routine clinical care and to complete some questionnaires remotely. If participants are willing to talk to us about their injury and taking part in research, we may invite participants for an interview and/or focus group.
The questionnaires are short and easy to complete and all reasonable expenses, such as travel and parking costs associated with attending the research clinic, patient interviews and focus groups will be fully reimbursed.

What are the possible benefits and risks of participating?
The information we get from this study will help us to improve treatment for other people like participants in the future.
Taking part in this study does not affect the usual care participants receive. We will just be monitoring how participants and their hand are recovering, so there are no risks to taking part in this study.

Where is the study run from?
This research is being organised by the University of Nottingham and will be recruiting patients from hand fracture clinics at Queen's Medical Centre, Nottingham and the Pulvertaft Hand Centre, Derby.

When is the study starting and how long is it expected to run for?
June 2020 to January 2022

Who is funding the study?
This study is funded by the National Institute for Health Research (NIHR).

Who is the main contact?
Miss Rowa Taha, FACTS-Study@nottingham.ac.uk

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
279115

Protocol serial number
IRAS 279115

Study information

Scientific Title
Fractures of Adult metaCarpal shafTS (FACTS): Surgical and non-surgical treatment for metacarpal shaft fractures in adults: an observational feasibility study

Acronym
FACTS

Study objectives
1. To investigate the feasibility and acceptability of conducting a pragmatic multi-centre randomised controlled trial (RCT) to assess the clinical and cost-effectiveness of surgical versus non-surgical treatment for metacarpal shaft fractures in adults.
2. To provide complementary, detailed and person-centred insight that will inform RCT design through the identification of barriers to participation amongst patients with metacarpal shaft fractures and to develop novel solutions to engage these cohorts in research.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/06/2020, Cambridge South Research Ethics Committee (The Old Chapel Royal Standard Place Nottingham NG1 6FS, UK; no telephone number provided; cambridgesouth.rec@hra.nhs.uk), ref: 20/EE/0124

Study design
Dual-centre prospective cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metacarpal shaft fractures of the finger digits in adults

Interventions
This is an observational study. Patients treated in the two participating centres will be recruited to the study. No additional interventions outside of routine care will be undertaken. The outcomes of interest include feasibility outcomes relating to; assessment of eligibility, recruitment and retention rates; completion of follow-up; evaluation of outcome measures and calculation of the minimal clinically important difference (MCID) for the primary outcome measures using quantitative and qualitative assessments and establishing the feasibility of data collection methods and appropriate time-points for use in a future trial.

A nested qualitative study consisting of two elements, patient interviews and focus groups, will be conducted to provide patient-centered insight into study procedures and explore the individual impact of the injury. Patients will be selected from the prospective cohort study and further written informed consent separately sought.

An economic evaluation to estimate costs of treatments for metacarpal shaft fractures through representative micro-costing will be undertaken. Resource use directly linked to the metacarpal shaft fractures and its sequela and/or complications over the 6 months of follow-up will be recorded for each participant.

A two by two by two factorial design randomised sub-study will be nested within the main cohort study. Once participants have consented to the cohort study or qualitative study, they will be randomised to a sub-study that will evaluate the use of text messages to maximise data collection and participant retention in the study. The interventions will be: frequency of SMS messages – participants will receive either fortnightly or monthly messages; two-way communication - text message requiring a response from the participant versus a notification message only; and personalisation - personalised text message versus a standard automated message.

Intervention Type
Other

Primary outcome(s)
Feasibility outcomes are:
1. Number and proportion of patients assessed for eligibility
2. Size of the eligible patient pool available for recruitment
3. Identification of primary outcome measures for use in a future RCT
4. Estimation of the minimal clinically important difference (MCID) for selected outcome measures
5. Completion of follow-up assessments
6. Evaluation of the use of text messages in optimising data collection and retention

Key secondary outcome(s))
1. Hand function at 6 weeks by measuring the range of motion and grip strength
2. X-rays taken as part of routine clinical care will be reviewed at the 6-week research clinic and the location, type of fracture, amount of shortening, angulation and presence of step-off deformity on the X-rays will be recorded.
3. Questionnaires, patient-reported outcome measures, consisting of the hand health profile of the Patient Evaluation Measure (PEM), Patient-Reported Outcomes Measurement Information

System Upper Extremity (PROMIS-UE), Shortened Disabilities of the Arm, Shoulder and Hand Outcome Measure (QuickDASH), European quality of life questionnaire (EQ-5D-5L) and the Global Rating of Change (GROC) scale will be collected at baseline, 6 weeks, 3 months and 6 months

Completion date
31/01/2022

Eligibility

Key inclusion criteria
1. Adults 16 years or older
2. Radiologically confirmed metacarpal shaft fracture
3. Acute metacarpal shaft fracture affecting the index to little finger(s), presenting within 10 days of injury
4. Willing and able to give informed consent
5. Ability to understand English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
108

Key exclusion criteria
1. Fracture(s) of the thumb
2. Fractures extending into the joint surface
3. Fracture(s) of the metaphyseal base and/or neck of the metacarpal
4. Fracture(s) associated with dislocation at the carpometacarpal joint or other adjacent joint dislocation
5. Open fractures
6. Undisplaced fractures, defined as those with a visible fracture line on radiographs but anatomical alignment, i.e. the bone fragments remain aligned with no evidence of movement of the fracture fragments on anteroposterior, lateral or oblique radiographs
7. Patients who would not be able to adhere to study procedures or complete the study questionnaires

Date of first enrolment

01/08/2020

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Pulvertaft Hand Centre
Royal Derby Hospital
Kings Treatment Centre (KTC) Level 2
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Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Not defined

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

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/06/2021	13/08/2021	Yes	No
Basic results		09/05/2024	09/05/2024	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version v1.0	07/04/2020	07/08/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes