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SUBMIT study: metacarpal fracture fixation

Submission date 19/11/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/11/2015	**Overall study status** Completed	
Last Edited 22/08/2016	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Metacarpal fractures, commonly called broken fingers, account for about 40% of all hand injuries. Although generally surgery isn't needed, when the break is particularly serious surgery may be required. In these cases, the broken sections of bone need to be surgically moved back into the correct place. They are then held in place by fixing a metal plate to the bone with screws, which stabilises the bone while it heals. Traditionally, the plate is held in place by fixing the screws above and below the fracture (bicortical fixation). Although this procedure is generally very reliable, the excess drilling could cause damage to the soft tissue of the hand. In this time of procedure it is very important that the screws are the correct size, as if they are not then this could also damage the surrounding soft tissue. Unicortical fixation is a new technique where the screw is only fixed to one side of the broken bone. This technique is much less complex than bicortical fixation, and so it could potentially cause less damage to the surrounding soft tissues in the hand. As only one hole is drilled, there are also less likely to be complications if the screw is not the right size. The aim of this study is to find out whether bicortical or unicortical fixation is better for patients in terms of recovery.

Who can participate?
Adults who have broken their fingers within 72 hours and are having plate fixation

What does the study involve?
Participants are randomly allocated to one of two groups who will each have a different type of ORIF surgery. Those in the first group have the bicortical fixation procedure, in which the plate screws into both sides of the broken bone. Those in the second group have the unicortical fixation procedure, in which the plate screws only onto one side of the bone. At 6 weeks and 6 months, participants attend follow-up appointments in order to assess how well their fracture has healed.

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

Where is the study run from?
University Hospitals Birmingham NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2015 to April 2018

Who is funding the study?
Royal Centre for Defence Medicine (UK)

Who is the main contact?
Mr Mark Foster

Contact information

Type(s)
Public

Contact name
Mr Mark Foster

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18642

Study information

Scientific Title
Stability of unicortical vs bicortical metacarpal internal fixation trial (SUBMIT)

Acronym
SUBMIT

Study objectives
The aim of this trial is to compare the functional outcomes and complications of patients having unicortical versus bicortical fixation for diaphyseal metacarpal fractures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Medical Research Ethics Committee, 19/11/2015, ref: 14/WM/1212

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Topic: Surgery; Subtopic: Surgery; Disease: All Surgery

Interventions
Participants are randomly allocated to one of two groups, who will receive a different type of open reduction internal fixation (ORIF) surgery.

Group 1: Participants undergo bicortical fixation (standard practice), in which both the dorsal and palmar cortices of the metacarpal are drilled though
Group 2: Participants undergo unicortical fixation, in which only the near cortex is drilled

Participants in both groups are followed up for 6 months to monitor recovery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Fracture union is assessed at 6 weeks and 6 months

Secondary outcome measures
1. Complication rate is monitored continually throughout study
2. Fluroscopy exposure is measured during surgery
3. Implant failure is measured at 6 weeks and 6 months
4. Post operative stiffness is measured at 6 weeks and 6 months
5. Surgical time is measured during surgery

Overall study start date
01/06/2015

Completion date
06/04/2018

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Metacarpal diaphyseal fractures that require plate fixation
3. Patients undergoing anaesthesia with axillary brachial plexus regional blocks
4. Acute injury (within 72 hours)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 290; UK Sample Size: 290

Key exclusion criteria
1. Under 18 years of age
2. Deemed not competent to sign the consent forms
3. Pathologic fracture or a previous fracture of the same metacarpal
4. Other injury to the same upper limb requiring surgery
5. Major nerve injury (e.g., median, ulnar or radial)
6. Multi-trauma or -fractured patient
7. Revision procedure
8. Pregnant patient
9. Current or prior history of malignancy

Date of first enrolment
01/06/2015

Date of final enrolment
06/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Birmingham NHS Foundation Trust
Plastic Surgery Department
Mindelson Way
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B15 2WB

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust

Sponsor details
NIHR SRMRC, Research and Development
Queen Elizabeth Hospital
Edgbaston
Edgbaston
England
United Kingdom
B15 2TH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Centre for Defence Medicine

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	18/08/2016		Yes	No
HRA research summary			28/06/2023	No	No