

# SUBMIT study: metacarpal fracture fixation

<b>Submission date</b> 19/11/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/11/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/08/2016	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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

University Hospital Birmingham NHS Foundation Trust

Plastic Surgery Department

Mindelson Way

Edgbaston

United Kingdom

B15 2WB

## 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  
Edgbaston  
Birmingham  
United Kingdom  
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?
<a href="#">Protocol article</a>	protocol	18/08/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No