

Comparison of Internal Fixation of Metacarpal and Phalangeal Fractures with Metal or Bioabsorbable Implants

Submission date 30/09/2004	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 29/06/2010	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0295132798

Study information

Scientific Title

Study objectives

Internal fixation of metacarpal and phalangeal fractures with bio-absorbable implants negates the need for removal of the implant, as with metallic implants, at a second operation with benefit to the patient and financial implications.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Injury, Occupational Diseases, Poisoning: Fractures

Interventions

Please note that as of 21/06/10 it has been confirmed that this trial was stopped due to lack of staff and resources.

Prospective Randomised Controlled Trial. Metal vs bioabsorbable implants.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Total active range of motion (TAM) of affected digit
2. Grip strength measured with Jamar instrument
3. Complication rate
4. Fracture union rate
5. Implant removal rate
6. Financial cost of each treatment group

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2004

Completion date

30/10/2004

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility**Key inclusion criteria**

50 patients with metacarpal and phalangeal fractures.

Sample size will take 12-18 months to recruit at current admission rates for the fractures being studied.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

50

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/03/2004

Date of final enrolment

30/10/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

c/o Secretary to Professor Griffin

Coventry

United Kingdom

CV1 4FH

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospitals Coventry and Warwickshire NHS Trust (UK)

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