

# Comparison of orthodontic and conventional wire IMF in the open and closed management of mandibular fractures: a two centre randomised trial

**Submission date**

29/09/2006

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

29/09/2006

**Overall study status**

Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**

23/04/2015

**Condition category**

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

☐ Record updated in last year

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Geraldine Brown

**Contact details**

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Whipps Cross Road

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E11 1NR

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Comparison of orthodontic and conventional wire IMF in the open and closed management of mandibular fractures: a two centre randomised trial

### Study objectives

To compare orthodontic fixation treatment in jaw fractures.

### 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: Mandibular fractures

### Interventions

Patients randomised into 2 groups: open or closed management of fracture using two different type of fixings, patient satisfaction questionnaire/VAS pain scores.

### Intervention Type

Procedure/Surgery

### Primary outcome measure

To evaluate the two forms of treatment for cost benefit to the NHS.

Outcome measures: theatre time, length of stay, amount of follow up, patient satisfaction and pain experienced.

### Secondary outcome measures

Not provided at time of registration

**Overall study start date**

01/06/2004

**Completion date**

01/06/2006

## **Eligibility**

**Key inclusion criteria**

150 patients 75 from this site. Included are all patients with a mandibular lower jaw fracture, over 16, no pre-existing dental disease, attending Whipps Cross NHS or Barts and the London NHS Trust.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

150

**Key exclusion criteria**

Under 16, pre-existing dental disease, multiple facial fractures, upper jaw fractures, alveolar fractures.

**Date of first enrolment**

01/06/2004

**Date of final enrolment**

01/06/2006

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**SSR Orthodontics**

London

United Kingdom

E11 1NR

## Sponsor information

**Organisation**

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

**Sponsor details**

The Department of Health, Richmond House, 79 Whitehall

London

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SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

Whipps Cross University Hospital NHS Trust (UK), NHS R&D Support Funding

## 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