

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
Registration date 29/09/2006	Overall study status Completed	☐ Protocol
Last Edited 23/04/2015	Condition category Injury, Occupational Diseases, Poisoning	☐ Statistical analysis plan
		☐ Results
		☐ 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

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Contact details

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Additional identifiers

Protocol serial number

N0080141034

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

SSR Orthodontics

London

United Kingdom

E11 1NR

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration