

Use of modified mandibular plate for fractured mandible.

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/04/2014	Condition category Oral Health	<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
N0205132373

Study information

Scientific Title

Study objectives

1. Does the modified plate enhance the ease of placement, reduce the risk of damage to the roots of teeth, damage to the inferior dental nerve in the canal and the mental nerve?
2. Does it avoid the requirement to place two plates?

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Oral Health: Oral medicine

Interventions

Randomised clinical trial.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Ease of placement assessed by reduction in time of placement.
2. Reduction in the manipulation of mental nerve - assessed by sensory testing of the lip pre and post operation.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2003

Completion date

01/09/2006

Eligibility

Key inclusion criteria

40 consecutive patients who have sustained a fractured mandible passing through the mental foramen are randomly allocated to have a standard plate and the modified plate.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

40

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2003

Date of final enrolment

01/09/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The Royal London Hospital

London

United Kingdom

E1 1BB

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

Government

Funder Name

Barts and The London 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