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Use of modified mandibular plate for fractured mandible.

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/04/2014	Oral Health	[ ] 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