ISRCTN63274027 https://doi.org/10.1186/ISRCTN63274027

# A randomised prospective trial comparing bioabsorbable versus titanium plates in the treatment of mandibular and zygomatic fractures

| | | |
|---|---|---|
| **Submission date**<br>29/09/2006 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>29/09/2006 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>26/10/2015 | **Condition category**<br>Oral Health | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Mr K Webster

**Contact details**
Maxillofacial Surgery
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N0265154611

# Study information

## Scientific Title
A randomised prospective trial comparing bioabsorbable versus titanium plates in the treatment of mandibular and zygomatic fractures

## Study objectives
Mandibular and zygomatic fractures are conventually fixed by open reduction and internal fixation using titanium plates and screws. Between 18-35% of these plates are subsequently removed due to complications such as loosening.
Bioabsorbable plates are now available as an alternative to metal plates. The potential advantage of using resorbable plates is that the reoperation rate to remove titanium plates that develop complications would be greatly reduced.
The Inion(R) bioabsorbable material comprises the polymers L-polylactic acid, D/L-polylactic acid, trimethylene carbonate and polyglycolic acid. The material degrades by hydrolysis into carbon dioxide and water, in a similar fashion to "dissolving" sutures. The degradation profile provides initial stability to the facial bone and then progressive.
Although bioabsorbable plates have been used in facial fractures there is no prospective data to confirm that they are equivalent to titanium plates. A prospective comparison of the two systems would define whether bioabsorbable plates have a lower complication rate and whether a reduction in reoperation rate can be achieved.

The Null hypothesis to be answered is: there is no difference in the re-operation rate in mandibular and zygomatic fracture repair between titanium and Inion(R) bioabsorbable plates.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Prospective single-blind randomised single-centre study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Oral Health

### Interventions
All patients presenting to the maxillofacial trauma service at University Hospital Birmingham with mandibular and maxillary fractures will be randomised to two treatment arms:
1. Conventional treatment with ORIF using titanium miniplates
2. ORIF using bioabsorbable plates

Invasive procedures and investigations: no change in pre-operative workup will be required
Duration of study: outpatient review at 1 week, 6 weeks, six months and 12 months
End points/outcomes: a comparison of complication rates in each group.
Expected complications: infection, loosening of plates and screws, plate fracture, plate exposure (in mouth), malunion, non-union of fracture

### Intervention Type
Procedure/Surgery

### Primary outcome measure
The rate of removal of resorbable vs non resorbable plates in facial fractures

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/03/2005

### Completion date
25/01/2008

## Eligibility

### Key inclusion criteria
1. Healthy adult volunteers
2. Traumatic mandibular or zygomatic fractures

### Participant type(s)
Patient

### Age group
Adult

### Sex
Not Specified

### Target number of participants
Not provided at time of registration

### Key exclusion criteria

1. Overt infection
2. Pregnancy
3. Under 16
4. Pathological fractures, prisoner, malignancy

### Date of first enrolment
01/03/2005

### Date of final enrolment
25/01/2008

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Queen Elizabeth Hospital**
Birmingham
United Kingdom
B15 2TH

## 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
United Kingdom
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**
University Hospital Birmingham 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