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

Submission date
29/09/2006

Registration date
29/09/2006

Last Edited
26/10/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] 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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Prospective single-blind randomised single-centre study

Study type(s)
Treatment

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(s)
The rate of removal of resorbable vs non resorbable plates in facial fractures

Key secondary outcome(s)
Not provided at time of registration

Completion date
25/01/2008

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham 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