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Efficacy and safety aspects of biodegradable fixation systems: a randomised clinical trial

Submission date 28/12/2006	**Recruitment status** No longer recruiting
Registration date 28/12/2006	**Overall study status** Completed
Last Edited 12/05/2017	**Condition category** Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

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
N/A

Study information

Scientific Title
Efficacy and safety aspects of biodegradable fixation systems: a randomised clinical trial

Acronym
FixITT

Study objectives
The performance of the Inion biodegradable osteofixation system is inferior compared to a titanium system regarding the treatment of zygoma, Le Fort I fractures, Le Fort I osteotomies, mandibula fractures and Bi-lateral Sagittal Split Osteotomies (BSSO) of the maxillofacial skeleton by healthy patients with regard to bone healing, stability and complications like, infections, plate dehiscence, hypersensitivity and palpability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medisch Ethische Toetsingscommissie Universitair Medisch Centrum Groningen, 01/05/2006, ref: 2006/035

Study design
Randomised controlled parallel-group double-blinded multicentre trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Maxillofacial trauma and orthognathic anomalies in the maxillofacial skeleton

Interventions
Fixing bone segments in the maxillofacial skeleton with titanium or biodegradable fixation devices.

Intervention Type
Procedure/Surgery

Primary outcome measure
Bone healing is the primary outcome measure. The definition of bone healing is: healing of the bone segments after eight weeks without clinical and radiological signs of disturbed bone healing.

Bone healing related complications are not allowed during this period.

Secondary outcome measures
1. Inflammatory reaction present (redness, swelling, sensitivity, warmth, function impairment, fistula or pus drainage), assessment visual and manually
2. Seriousness inflammatory reaction (mild, serious), assessment visual and manually
3. Palpability, assessment manually
4. Dehiscence, assessment visual
5. Occlusion, assessment visual
6. Bone formation (screw holes, fracture crevice)
7. Pain, evaluated by a Visual Analogue Scale (VAS)
8. Cold/warm sensitivity
9. Mandibular function, evaluated by a Mandibular Function Impairment Questionnaire (MFIQ)
10. Direct costs within the health care
11. Direct costs outside the health care
12. Indirect costs outside the health care
13. Antibiotic use
14. Analgesic use
15. Re-operation required
16. Reasons re-operations (plate/screw exposition, plat/screw fracture, loosening of plates and screws, inadequate bone healing, inadequate reduction, infection or other reasons)

Overall study start date
01/10/2006

Completion date
01/10/2008

Eligibility

Key inclusion criteria
1. Patients scheduled for a solitair Le Fort I fractures, and/or
2. Patients scheduled for a solitair of multiple mandibula fracture(s), and/or
3. Patients scheduled for a solitair zygoma fracture, and/or
4. Patients scheduled for a Le Fort I osteotomy, and/or
5. Patients scheduled for a BSSO
6. Patients who signed the informed consent form

Participant type(s)
Patient

Age group
Not Specified

Sex

Not Specified

Target number of participants
230

Key exclusion criteria
1. Severe chronically ill patients (i.e.. diabetes mellitus)
2. Patients by whom compromised bone healing has been established (i.e. osteoporosis)
3. Patients who are submerged through an infection
4. Patients who are pregnant
5. Patients who could not participate in a long follow-up (reasons)
6. Patients who already have received maxillary surgery in the past (i.e,. schisis)
7. Patients who are diagnosed with a psychiatric disorder (diagnosed by a psychiatrist)
8. Patients who will not agree with a random assignment to one of the treatment groups or one of the methods of treatment used in the study
9. Patients younger than 18 years regarding patients treated for fractures and patients younger that 14 regarding patients treated for osteotomies

Date of first enrolment
01/10/2006

Date of final enrolment
01/10/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen (UMCG)
Groningen
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9700 RB

Sponsor information

Organisation
University Medical Center Groningen (UMCG) (The Netherlands)

Sponsor details
Department of Oral and Maxillofacial Surgery
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Sponsor type
Hospital/treatment centre

Website
http://www.rug.nl/umcg/index?lang=en

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Industry

Funder Name
Stryker Nederland (The Netherlands)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2012		Yes	No
Results article	results	01/12/2013		Yes	No
Results article	results	20/07/2015		Yes	No
Results article	results	11/05/2017		Yes	No