

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

Submission date 28/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/05/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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 than 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

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Center Groningen (UMCG) (The Netherlands)

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Industry

Funder Name

Stryker Nederland (The Netherlands)

Results and Publications

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