Efficacy and Safety Aspects of Biodegradable Fixation Systems: a Randomized Clinical Trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27878

Source
NTR

Brief title
FixITT

Sponsors and support

Primary sponsor: Stryker Nederland
Source(s) of monetary or material Support: In process

Intervention

Outcome measures

Primary outcome

Bone healing is the primary outcome measure. The definition of bone healing is: healing of the bone segments after 8 weeks without clinical and radiological signs of disturbed bone healing. Bone healing related complications are not allowed during this period.

Secondary outcome

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.
bone formation (screw holes, fracture crevice);

6. pain, evaluated by a Visual Analogue Scale (VAS);

7. cold/warm sensitivity;

8. mandibular function, evaluated by a Mandibular Function Impairment Questionnaire (MFIQ).

9. direct costs within the de health care;

10. direct costs outside the health care;

11. indirect costs outside the health care.

12. antibiotic use;

13. analgesic use;

14. re-operation required;

15. reasons re-operations (plate/screw exposition, plat/screw fracture, loosening of plates and screws, inadequate bone healing, inadequate reduction, infection or other reasons).

Study description

Background summary

The aim of this multi-center randomized clinical trial is to investigate the efficacy and safety aspects of the Inion biodegradable osteofixation system in comparison to a titanium system for the treatment of maxillofacial traumata and orthognatic anomalies in the maxillofacial skeleton.

The research population consists of patients who are scheduled for treatment of

1. zygoma fractures,

2. Le Fort I fractures,

3. Le Fort I osteotomies,

4. mandibular fractures and

5. Bi-lateral Sagittal Split Osteotomiës (BSSO).

The patients (blinded for treatment group) will be assigned at random to a titanium and a degradable group. Bone fixation by patients in the biodegradable group will be done with the Inion degradable fixation system. The used titanium system will be a conventional system. The two treatment modalities (biodegradable versus titanium) will be compared at non-inferiority level. The reason for this is that bone segments fixed with biodegradable plates and screws must heal as good as bone segments fixed with titanium plates and screws.

Bone healing is the primary outcome measure. The definition of bone healing is:
healing of the bone segments after 8 weeks without any clinical and radiological signs of disturbed bone healing. The secondary outcome measures contain the following aspects: inflammatory reaction present, seriousness inflammatory reaction, palpability, dehiscence, occlusion, bone formation, pain, cold/warm sensitivity, mandibular function, and costs.

Study objective

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 en bi-lateral sagittal split osteotomies of the maxillofacial skeleton by healthy patients with regard to bone healing, stability and complications like, infections, plate dehiscence’s, hypersensitivity and palpability?

Intervention

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

Contacts

Public
University Medical Center Groningen (UMCG)
Department of Oral Sugery
P.O. Box 30001
G.M. Raghoebar
Groningen 9700 RB

The Netherlands
+31(0)50 3613186
Scientific
University Medical Center Groningen (UMCG)
Department of Oral Sugery
P.O. Box 30001
G.M. Raghoebar
Groningen 9700 RB
The Netherlands
+31(0)50 3613186

Eligibility criteria

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, and/or;

6. patients who signed the informed consent form.

Exclusion criteria

1. severe chronically ill patients (i.e.. diabetis mellites);

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 an at random assignment to one of the treatment groups or one of the methods of treatment used in the study;

9. patients younger than 18 year regarding patients treated for fractures and patients younger that 14 regarding patients treated for osteotomies.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2006
Enrollment:	230
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL761
NTR-old	NTR772
Other	: N/A
ISRCTN	ISRCTN44212338

Study results

Summary results
N/A