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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27878

Bron
NTR

Verkorte titel
FixITT

Ondersteuning

Primaire sponsor: Stryker Nederland
Overige ondersteuning: In process

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksproduct en/of interventie

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

devices.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2006
Aantal proefpersonen:	230
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-09-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A