Onderzoek naar op maat gemaakte botfixatieplaten voor de kaak

Gepubliceerd: 03-06-2021 Laatst bijgewerkt: 18-08-2022

It is our hypothesis that the patient receiving patient specific osteosynthesis will have a more accurate result.

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

Samenvatting

ID

NL-OMON26857

Bron
NTR

Verkorte titel
TBA

Aandoening

Dysgnatic patients

Ondersteuning

Primaire sponsor: Department of Oral and Maxillofacial Surgery of University Medical Center Groningen
Overige ondersteuning: Eerste geldstroom & Derde geldstroom namelijk deelfinanciering vanuit PPP-Allowance

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary study parameter is the median difference between planned and realised

positioning of the maxilla, measured at the level of the dentition.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In orthognathic surgery, patients with a dysgnatic deformity are operated to correct their functional and esthetical problems by realigning the mandible and/or maxilla. Recently, colleagues Kraeima et al. have shown promising results by realigning the maxilla using patient specific osteosynthesis (PSO); it improves the accuracy of maxillary translations when compared with the conventional method using manually bent osteosynthesis. In a selection of orthognathic patients, both the upper and lower jaw are operated on, so called bimaxillary surgery. The current study is a follow-up study, where bimaxillary surgery is included in the scope.
In the field of bimaxillary surgery, a much debated question is the order of sequencing the operation, either maxilla-first or mandibula-first. Traditionally, the maxilla is first operated on, followed by the mandible. However, a mandible first approach could theoretically be more precise due to a better condylar seating of the mandible then positioning of the maxilla. Reviewing literature on orthognathic sequencing, there is still limited consensus on which approach can provide the most predictable result.
From the study by colleague Kraeima we can derive an increased accuracy when using PSO compared with conventional maxilla-first surgery. However, the mandible-first sequence was not considered. Seeing the limited consensus in literature on the best sequencing approach, the question is raised whether PSO can increases the accuracy and predictability of 3D planned orthognathic bimaxillary surgery, also when compared with the mandible-first approach. Current data on the accuracy of mandible-first surgery and PSO are not directly comparable; as such an analysis has not yet been reported.

Objective: The primary objective of this study is to answer if PSO increases the accuracy and predictability of 3D planned orthognathic bimaxillary surgery compared to conventional bimaxillary surgery using the mandible-first approach and mini-plate fixation. The secondary objective of this study is to answer if PSO influences the one-year follow-up skeletal stability of the maxillary segment compared to conventional osteosynthesis using mini-plate fixation

Study design: In order to test the difference in accuracy of translation of 3D virtual planning and predictability of outcome, this study requires a randomised controlled prospective trial design. The control group will receive conventional 3D virtually planned mandible-first translation guided by 3D splints and fixed with conventional osteosynthesis and the intervention group will receive 3D virtually planned translation guided patient specifically using maxillary drill- and saw guides and PSO.

Study population: All consecutive patients who will undergo a bimaxillary osteotomy due to a dysgnatic deformities, when eligible according to the inclusion/exclusion criteria, will be asked to participate in this study.

Study site: 1) Department of Oral and Maxillofacial surgery at the University Medical Center Groningen 2) Department of Oral and Maxillofacial surgery at the Martini Hospital Groningen.

Intervention: The intervention in this study is an osteotomy of the upper and lower jaw (bimaxillary osteotomy), performed using patient specific drill- and saw surgical guides and PSO of the maxilla in the intervention group. The control group will receive a care as usual mandible-first osteotomy using splints and conventional osteosynthesis.

Main study parameters/endpoints: The primary endpoint for this study is the geometrical change on dentition level. The baseline is the planned position, compared with the post-operative final position determined from CBCT. CBCT's of the maxillofacial region will be made according to care as usual in our clinic; pre-operative, 1-wk post-operative, 1-yr post-operative.

Doel van het onderzoek

It is our hypothesis that the patient receiving patient specific osteosynthesis will have a more accurate result.

Onderzoeksopzet

Follow-up after 2 weeks and one year

Onderzoeksproduct en/of interventie

Controle = Bimaxillary osteotomy with conventional mandible-first approach using splint and stock osteosynthesis, Intervention = Bimaxillary osteotomy with patient specific osteosynthesis guided maxilla-first approach.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• The patient is awaiting orthognathic surgical treatment, namely: bimaxillary osteotomies (upper and lower jaw) as part of their treatment plan;
• The patient is at least 18 years of age. Completion of physical growth is a routine criterion for orthognathic surgery;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Patient does not agree to randomized application of osteosynthesis method;
• Pregnancy, which is a general contraindication for orthognathic surgery;
• Known allergy to titanium
• Patient is, for any reason, not able to undergo the 3D virtual planning procedure, including double dentition imprints/intra-oral scan, pre-operative CBCT scanning and virtual planning of translations. An example could be the inability to complete the dental imprint of both upper and lower jaw, or inadequate scanning of the patient. These examples will. If applicable, come up during the preparation appointment with the patient, and therefore do not delay the patient’s trajectory.
• Patient has a cleft lip or cleft palate
• Patient has a syndrome associated with craniofacial anomalies
• The operation of the patient includes a multisegmental Le Fort 1 osteotomy of the maxilla

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-06-2021
Aantal proefpersonen:	88
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-06-2021
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	NL9552
Ander register	METC UMCG : METC.2020.537

Resultaten