Improving accuracy of genioplasty in orthognathic surgery with a patient-specific guidance system: a randomized intervention study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20442

Source
Nationaal Trial Register

Brief title
Patient-specific guides for genioplasty

Health condition

Orthognathic surgery

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Accuracy of the execution of the genioplasty

Secondary outcome

Surgery time

Study description

Background summary

In this study, we investigate whether or not the accuracy of genioplastic surgery improves with the use of patient specific cutting/positioning guides.
The positional changes of the chin segment are nowadays planned using 3D computer technique. Compared to the older 2D planning the complexity of the planning has increased dramatically. To transfer the 3D computer plan to the patient during the surgery patient specific guides are frequently used. It is not known if these guides actually improve the accuracy.

Study objective

Application of patient-specific guides will improve the accuracy of the execution of the genioplasty

Study design

Before surgery: preoperative (CB)CT scan
Surgery: surgery time
After surgery: postoperative (CB)CT scan

Intervention

Execution of genioplastic surgery with patient-specific cutting and repositioning guides versus conventional method (without guides)

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Older than 18 years
• Genioplasty indicated in 3D preoperative planning.

Exclusion criteria

A potential subject will be excluded from participation in this study when the surgery is indicated for any of the following conditions:
• Congenital disorders (e.g. craniofacial microsomia)
• Obstructive Sleep Apnea Syndrome (OSAS)
• Transgender surgery
• Previous orthognathic surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2020

Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55324
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8332
CCMO	NL72676.018.20
OMON	NL-OMON55324

Study results