

Velopharyngeal insufficiency after maxillomandibular advancement in obstructive sleep apnea patients

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To examine the course of velopharyngeal insufficiency after maxillomandibular advancement in patients with obstructive sleep apnea.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON57175

Source

ToetsingOnline

Brief title

Velopharyngeal insufficiency after maxillomandibular advancement

Condition

- Respiratory tract therapeutic procedures

Synonym

nasality, speech, swallowing, Velopharyngeal insufficiency

Research involving

Human

Sponsors and support

Primary sponsor: MKA-chirurgie

Source(s) of monetary or material Support: in kind afdeling MKA-chirurgie

Intervention

Keyword: maxillomandibular advancement, Obstructive sleep apnea, Velopharyngeal insufficiency

Outcome measures

Primary outcome

Objective outcomes:

- Nasality

Secondary outcome

Objective outcomes:

- Swallowing
- Speech

Subjective outcomes:

- Nasality
- Swallowing
- Speecht
- Regurgitation
- Quality of life
- neurosensory disturbance

Study description

Background summary

Maxillomandibular advancement (MMA) is a successful surgical treatment for patients with moderate to severe obstructive sleep apnea (OSA). It is a form of orthognathic surgery and it includes forward repositioning of the maxilla and

mandible to put more tension on the soft tissue and widening the upper airway. This results in improvement of polysomnography outcomes, sleep and quality of life. After the surgery change in velopharyngeal symptoms, such as nasality, swallowing and speech, could exist. Some patients found improvement velopharyngeal insufficiency (VPI), however other patients develop VPI. (Li). There are some studies that describe VPI after orthognathic surgery in cleft palate patients. However little is known about VPI after MMA in patients with OSA. Using objective and subjective measurement methods, we can examine the course of VPI after an MMA. With this understanding, we can better prepare patients for the postoperative symptoms of an MMA. In addition, patients could be better managed with speech therapy postoperatively.

Study objective

To examine the course of velopharyngeal insufficiency after maxillomandibular advancement in patients with obstructive sleep apnea.

Study design

Prospective cohort study

Study burden and risks

All test are non invasive. There will be no physical and physiological discomfort. The extra burden and risk associated with this study are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

Patients with obstructive sleep apnea who undergo maxillomandibular advancement osteotomy as treatment

Exclusion criteria

- Patients who underwent other adjunctive procedures at the time of MMA (e.g., multipiece Le Fort osteotomy, TMJ reconstruction)
- Previous history of orthognathic surgery
- Previous history of oropharyngeal surgery (UPPP or multilevel surgery)
- Cleft palate and syndromic patients
- Neuromusculair diseases which causes VPI, dysphagia or dysarthria
- incapacity

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-01-2025
Enrollment: 28
Type: Anticipated

Ethics review

Approved WMO
Date: 28-10-2024
Application type: First submission
Review commission: METC Amsterdam UMC

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
CCMO	NL83076.018.23