

advancement of the mandible by bilateral sagittal split osteotomy and distraction osteogenesis; a randomised clinical trial

Published: 13-09-2007

Last updated: 09-05-2024

To evaluate the two procedures for lengthening of the mandible.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON31250

Source

ToetsingOnline

Brief title

BSSO versus DOG for advancement of the mandible

Condition

- Musculoskeletal and connective tissue disorders congenital
- Bone and joint therapeutic procedures

Synonym

hypoplastic mandible

Research involving

Human

Sponsors and support

Primary sponsor: Isala klinieken Zwolle, locatie Weezenlanden

Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: complication, distraction osteogenesis, mandible, osteotomy

Outcome measures

Primary outcome

Sensory disturbances in the lower lip.

Secondary outcome

Stability

Complications

Costs

Study description

Background summary

There are two surgical procedures for a mandibular advancement. The (dis) advantages of these procedures in comparison with each other are not clear.

Study objective

To evaluate the two procedures for lengthening of the mandible.

Study design

Randomized clinical trial.

Intervention

BSSO or DOG

Study burden and risks

No extra controle visits or X-rays. A few questionnaires and sensory tests will be done.

Contacts

Public

Isala klinieken Zwolle, locatie Weezenlanden

Groot Wezenland 20

8011 JW Zwolle

Nederland

Scientific

Isala klinieken Zwolle, locatie Weezenlanden

Groot Wezenland 20

8011 JW Zwolle

Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

hypoplastic mandible

Exclusion criteria

advancement of more than 12 mm

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 26-03-2008

Enrollment: 90

Type: Actual

Ethics review

Approved WMO

Date: 13-09-2007

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

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

CCMO

ID

NL18755.075.07