Does speech therapy improve the subjective function of the inferior alveolar nerve after a permanent paresthesia due to an advancement procedure of the mandible.

Published: 30-10-2008
Last updated: 06-05-2024

Improvement of the discomfort of the paresthesia, as experienced by the patient.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON31963

Source
ToetsingOnline

Brief title
Does speech therapy improve the function of the inferior alveolar nerve

Condition

- Peripheral neuropathies

Synonym
disesthesia, paresthesia

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: maatschap kaakchirurgen en vakgroep logopedie

Intervention

Keyword: inferior alveolar nerve, mandible, paresthesia, speech therapy

Outcome measures

Primary outcome

Improvement of the discomfort of the paresthesia, as experienced by the patient

after 3 months..

Secondary outcome

Improvement of the results of the neuro-sensibility tests after 3 months.

Improvement of sensibility, as experienced by the patient, after 3 months

Mean difference in discomfort after 6 months.

Mean difference in the results of the neuro-sensibility tests after 6 months.

Mean difference of sensibility, as experienced by the patient, after 6 months.

Study description

Background summary

An advancement procedure of the mandible is a routine operation in oral and maxillofacial surgery. More than 50 of these procedures are performed in the Isala Klinieken every year. The mean complication in patients who underwent this operation is a permanent dysfunction in the inferior alveolar nerve, that can possibly lead to problems in eating or speaking, due to a lack of neuro-sensory feedback in the oral region. Incidence rate of this complication is about 15-20%, which means that 8-10 patients a year experience this discomfort. Recently, several patients have been treated by a speech therapist with a significant positive improvement in oral function and a diminished discomfort from the paresthesia.
In current literature there is no data available on this myofunctional therapy, therefore, this promising new treatment option needs to be evaluated in a

clinical trial.

Study objective

Improvement of the discomfort of the paresthesia, as experienced by the patient.

Study design

Study design is a parallel randomized study. Randomization will take place after informed consent by the patients. Patients allocated for speech therapy will receive 5 sessions of therapy for 10 weeks. Treatment group will be evaluated before start of treatment, at the end of treatment and after 3 months. The control group will start therapy after 3 months and will be evaluated at the start of the control period, after 3 months at the end of the control period (start of treatment) and after 6 months at the end of therapy.At these time points, each patients will receive a VAS score questionnaire and will be subjected to neuro-sensibility tests.

Study burden and risks

Minimal, only 5 therapy sessions with the speech therapist and 3 evaluations.

Contacts

Public
Isala Klinieken

Groot Wezenland 20
8000GM Zwolle
NL
Scientific
Isala Klinieken

Groot Wezenland 20
8000GM Zwolle
NL

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

- BSSO or DOG procedure, after orthodontic treatment.
- Paresthesia of the inferior alveolar nerve, present for more than one year.

Exclusion criteria

- Pre-existing dysfunction of the inferior alveolar nerve.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2009
Enrollment:	54

Type:	Actual

Ethics review

Approved WMO Date:	30-10-2008
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	ID
CCMO	NL23638.075.08