Taste, Speech and oro-facial relations following partial tongue reduction: A single-center, longitudinal, functional outcome study in patients with Beckwith-Wiedemann Syndrome that have undergone tongue reduction surgery

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The aim of this study is to investigate the long-term outcomes in patients with BWS that have been surgically treated at our institution with the help of simple, non-invasive, objective study tools. We hope to gain valuable information regarding the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON36543

Source
ToetsingOnline

Brief title
TAste, Speech and TEeth after tongue reduction surgery
TASTE-study

Condition

- Congenital and hereditary disorders NEC
- Head and neck therapeutic procedures

Synonym
Congenital enlarged tongue

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: persoonlijke subsidie van uitvoerend onderzoeker

Intervention

Keyword: Beckwith Wiedemann Syndrome, Macroglossia, Tongue Surgery

Outcome measures

Primary outcome

In total, all participants will visit the outpatient clinic of our craniofacial

research unit one single time to complete the study. Differences in the outcome

of the taste test, the speech assessment test and the evaluation of the

oro-facial development between the study group and the none-operated control

group will be evaluated.

Secondary outcome

Niet van toepassing

Study description

Background summary

Reports on the long-term functional outcomes of surgical tongue reduction in patients with Beckwith Wiedemann Syndrome are sparse and show various results. The evaluation of tongue function after tongue reduction surgery has been mainly subjective in previously published reports. The major difficulties when investigating the long-term functional outcomes after tongue reduction surgery remain the small number of treated patients and the need of validated tests for correct assessment of tongue function and taste.

Study objective

The aim of this study is to investigate the long-term outcomes in patients with BWS that have been surgically treated at our institution with the help of simple, non-invasive, objective study tools. We hope to gain valuable information regarding the benefits and possible disadvantages following tongue surgery, and to create a basis for further research investigating the surgical treatment options of macroglossia in Beckwith Wiedemann Syndrome.

Study design

A retrospective observational case-control follow-up study.

Study burden and risks

Participants will visit the outpatient clinic of our craniofacial research unit one single time. The risks are negligible and the burden minimal. We will be obliged to include minors as participants in our study since BWS is an uncommon disorder with a consequent limited number of potential participating patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Written informed consent
- History of macroglossia
- Patients included in the control group have been diagnosed with BWS and were not treated for macroglossia
- 5 years <= age <= 20 years on the day of participation
- History of good physical and mental health as determined by history taking.

Exclusion criteria

- Serious mental impairment
- History or presence of a medical condition that can influence speech, such as cleft palate, hearing problems or other problems that can potentially cause a developmental delay
- History or presence of a medical condition that can potentially influence taste perception
- History or presence of a medical condition that can potentially influence normal oro-facial development

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

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	NL35313.018.11