Ethanol submandibular duct ligation for drooling in children with neurodisabilities

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50942

Source
ToetsingOnline

Brief title
Ethanol 2-duct ligation

Condition

- Other condition
- Chromosomal abnormalities, gene alterations and gene variants
- Congenital and peripartum neurological conditions

Synonym
Drooling

Health condition

Speeksekliered

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Gelden uit eerder verworven beurzen

Intervention

Keyword: Cerebral palsy, Drooling, Neurodisabilities, Surgery

Outcome measures

Primary outcome

The primary aim of this study is to evaluate the safety (adverse events and

complaints) of the procedure which is defined by adverse events and

post-operative complaints (i.e. safety), and surgical time.

Secondary outcome

Secondary outcomes include the suitability for an out-patient procedure.

Study description

Background summary

drooling is associated with physical, psychosocial, and emotional distress. Previous studies revealed that submandibular duct ligation (2-DL) is an effective and safe treatment for drooling in neurodisabilities. However, a quarter of patients recurred in the period between week 8 and 32 weeks after 2-DL. Alternative salivary pathways were proposed as leading reason for recurrence and treatment failure of 2-DL. Recent literature illustrated that intraductal ethanol infusion in the salivary gland is safe and effective for the treatment of drooling.

Study objective

the primary aim of this study is to evaluate the safety (adverse events and complaints) of submandibular duct ligation right after intraductal ethanol infusion into the submandibular salivary gland (Ethanol two-duct ligation [E-2DL] in order to improve treatment effect, and prevent recurrence and

alternative salivary pathways after 2-DL. The secondary aims of the study are to evaluate effect, and to evaluate whether an out-patient setting is suitable for the procedure.

Study design

Prospective pilot study

Intervention

submandibular duct ligation right after intraductal ethanol infusion into the submandibular salivary gland.

Study burden and risks

We expect some additional swelling of the submandibular region. There is some risk for extravasation which could incude additional post-operative zwelling. To minimize swelling we will prescribe per-operative medication. To prevent extravasation, we will control infusion under sialography.

The benefit of the addition of Ethanol to submandibular duct ligation is that we expect better treatment effect.

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)

Inclusion criteria

1. Moderate to severe drooling indicated by Drooling Frequency Score >= 3 or Drooling 370 Severity Score >= 2. 371
2. Aged 10 years and older. 372
3. Cerebral palsy or any other non-progressive neurodevelopmental disability. 373
4. Contra-indications for a SMDR, or rejection towards a SMDR by patient or caregivers* 374
5. Ability and willingness to follow the study protocol and attend the 8 and 32-weeks vis-375 its. 376
6. Written and informed consent from caregivers, and when appropriate, oral consent 377 from the child.

Exclusion criteria

1. Medical history of salivary gland abnormalities like ductal stenosis, strictures
2. Previous submandibular salivary gland surgery, or other contraindications for surgery 385 or general anesthesia. 386
3. Recent (<6 months) glandular Botulinum Neurotoxin A (BoNT-A) injection 387
4. Simultaneous alternative treatment for drooling.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Ethanol 96%
Generic name:	Alcohol 96%
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	30-07-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-02-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2021-004057-23-NL
CCMO	NL77138.091.21