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Breastfeeding and reflux improvement, the effect of frenulotomy

Submission date
30/08/2017

Recruitment status
No longer recruiting

Registration date
21/09/2017

Overall study status
Completed

Last Edited
01/10/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The World Health Organization recommends breastfeeding babies for at least six months. Unfortunately, due to breastfeeding problems, this is often not possible. There are many different causes of breastfeeding problems, including poor weight gain necessitating supplementation, poor latch, maternal nipple pain, and structural restrictions like a tongue tie (ankyloglossia) and/or lip tie. This is when the tongue has limited movement because the strip of skin that connects the baby's tongue to the mouth is shorter than usual. Previous studies showed that a tongue tie (ankyloglossia) and/or a lip tie (tethered superior labial frenum) can cause altered latch and sucking mechanics. The suckling process is complex and multi-factorial, and dysfunction may cause diverse signs and symptoms in the breastfed baby. A frenectomy is a procedure that removes the piece of skin to allow more movement in the tongue. This study aims to examine the effect on breastfeeding improvement and reflux problems after a frenectomy of ankyloglossia and/or tethered maxillary labial frenula.

Who can participate?
Newborns under six months with untreated ankyloglossia and/or tethered maxillary labial frenula with breastfeeding (and reflux) problems.

What does the study involve?
Participants are asked to fill in questionnaires to examine breastfeeding improvement, reflux improvement and to describe pain during breastfeeding. Prior to the surgery a small amount of topical anesthetic cream (a numbing cream) is placed on the tongue and/or lip tie. Participants then receive the frenulotomy with diathermy done to the standard procedure. Participants are followed up was after one week, one month and six months with the same questionnaires.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating in the study, as the procedure is part of the standard procedure treating a tongue or lip tie.

Where is the study run from?
University Medical Centre Groningen (The Netherlands)

When is the study starting and how long is it expected to run for?
September 2017 to December 2018

Who is funding the study?
University Medical Centre Groningen (The Netherlands)

Who is the main contact?
Dr Kirsten Slagter
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
METc 2014/375

Study information

Scientific Title
Breastfeeding improvement after frenectomy tongue- and lip tie

Acronym
BOEFjes study

Study objectives
The aim of this study is to examine the effect on breastfeeding improvement and reflux problems after a frenectomy of ankyloglossia and/or tethered maxillary labial frenula.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Medical Ethical Board of the University Medical Centre Groningen, 11/09/2014, ref: METc 2014 /375

Study design
Single centre prospective observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Newborns with untreated ankyloglossia and/or tethered maxillary labial frenula with breastfeeding (and reflux) problems.

Interventions
Study enrollment and informed consent were completed subsequent to standard surgical consent. Participants were orally examined if restrictions were present and standardized classification systems were used to describe frenula anatomy. Breastfeeding mothers were asked to fill in questionnaires to examine Breastfeeding improvement (BSES-SF (Breastfeeding Self-Efficacy Scale Short Form questionnaire)), Reflux improvement (I-GERQ-R (Infant-Gastroesophagal Reflux Questionnaire- Revised)) and to describe pain during breastfeeding with the Visual Analogue Scale (VAS). Prior to the surgery a small amount of topical anesthetic cream was placed on the tongue and/or lip tie.

Participants receive a surgical procedure called a frenulotomy of a tied tong tie and/ or lip tie. Frenectomy of the untreated ankyloglossia and/or tethered maxillary labial frenula. The frenulotomy is performed by using diathermy. The duration of the surgery is 10 seconds with the use of surface anesthesia, and the follow-up for all patients is after one week, one month and 6 months. Participants are followed up to see if breastfeeding has improved using the same questionnaires.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Breastfeeding improvement is measured using the BSES-SF (Breastfeeding Self-Efficacy Scale Short Form) questionnaire at one week, one month and six months.

Key secondary outcome(s))
1. Reflux improvement is emasured using the I-GERQ-R (Infant-Gastroesophagal Reflux Questionnaire- Revised) at one week, one month and six months
2. Pain during breastfeeding is measured using the Visual Analogue Scale (VAS) at one week, one month and six months.

Completion date
01/12/2018

Eligibility

Key inclusion criteria
1. Newborns under 6 months
2. Are breast fed
3. Untreated ankyloglossia and/or tethered maxillary labial frenula

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
175

Key exclusion criteria
1. Older then 6 months
2. Premature born
3. Unhealthy
4. Formula fed
5. Already revised ankyloglossia and/or tethered maxillary labial frenula

Date of first enrolment
01/10/2017

Date of final enrolment
01/06/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Groningen
Hanzeplein 1
Groningen
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9700 RB

Sponsor information

Organisation
University Medical Centre Groningen

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Groningen

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from dr.K.W.Slagter, DDS,PhD at info@boefjesstudie.nl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	26/01/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes