

# Breastfeeding and reflux improvement, the effect of frenulotomy

<b>Submission date</b> 30/08/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/01/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The World Health Organization recommends breastfeeding babies for at least for six months. Unfortunately, due to breast-feeding problems, this is often not possible. There are many different causes of breast-feeding problems and include 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 due to 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 removed the piece of skin to allow more movement in the tongue. 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.

### 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 (Switzerland)

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 (Switzerland)

Who is the main contact?  
Dr Kirsten Slagter  
info@boefjesstudie.nl

**Study website**  
www.boefjesstudie.nl

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Kirsten Slagter

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**Secondary study design**

Cohort study

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

Participant information sheet can be found at the following website: [www.boefjesstudie.nl](http://www.boefjesstudie.nl)

**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-Gastroesophageal 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 tongue 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 measure**

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

**Secondary outcome measures**

1. Reflux improvement is measured using the I-GERQ-R (Infant-Gastroesophageal 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.

**Overall study start date**

01/09/2017

**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

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

152

**Total final enrolment**

175

**Key exclusion criteria**

1. Older than 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

Netherlands

9700 RB

## **Sponsor information**

### **Organisation**

University Medical Centre Groningen

### **Sponsor details**

Hanzeplein 1

Groningen

Netherlands

9700RB

### **Sponsor type**

Hospital/treatment centre

### **Website**

[www.umcg.nl](http://www.umcg.nl)

### **ROR**

<https://ror.org/03cv38k47>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

University Medical Centre Groningen

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal one year after the trials. A short summary of the protocol in Dutch is online at [www.boefjesstudie.nl](http://www.boefjesstudie.nl)

## Intention to publish date

01/12/2019

## 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](mailto:info@boefjesstudie.nl)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2020	26/01/2021	Yes	No