ISRCTN10268851 https://doi.org/10.1186/ISRCTN10268851

A randomised controlled trial of frenotomy or breastfeeding support for babies with tongue-tie

Submission date
04/02/2019

Recruitment status
No longer recruiting

Registration date
15/02/2019

Overall study status
Completed

Last Edited
26/07/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
This is a study for babies with breastfeeding difficulties who are thought to have tongue-tie. Many mothers and babies experience difficulties in establishing breastfeeding. In some babies it is thought that their difficulties may be linked to a condition called tongue-tie, in which a piece of skin tightly joins the middle part of the underside of the tongue to the base of the baby's mouth. This can be treated by an operation to divide the tight part/skin in the middle of the underneath of the tongue. It is usually carried out as an outpatient by either a midwife or doctor and babies typically go home the same day. However, there are other reasons for breastfeeding difficulties, including poor positioning and attachment of the baby to the breast. These difficulties can be solved by support from skilled infant feeding counsellors, and it may be that being given this support is more useful to help mothers and babies to continue to breastfeed when the baby is thought to have a tongue-tie and an operation is not needed. The aim of this study is to see whether an operation makes a difference to mothers and their babies. The study will compare babies in the group who have the operation and breastfeeding support to babies in the group who only receive breastfeeding support but not an operation. The main outcome is to compare how many babies in each group are still breastfeeding at three months.

Who can participate?
Babies aged up to 10 weeks with breastfeeding difficulties diagnosed with a tongue-tie are eligible for inclusion, as long as their parents give consent to do so. Some babies will not be able to take part in the trial, for example babies born at less than 34 weeks' gestation, or if they have a known bleeding disorder, or if they have another condition known to affect breastfeeding (e.g. cleft palate, Down syndrome).

What does the study involve?
After parents have been given information about the trial and decided that they would like their baby to take part, the baby is allocated at random (similar to tossing a coin) to either have an operation or not. All babies receive breastfeeding support whether or not they have an operation. When all the babies in the study are three months old, their mothers are asked whether they are still breastfeeding. Information is also collected about the age of the baby at

his/her last breastfeed, the baby's weight, any problems the baby had after the operation, whether the mothers have any breastfeeding difficulties e.g. pain or are anxious or depressed, and how confident they feel about breastfeeding. This information is compared between the two groups to see if there are any differences between the babies in the group who had an operation straightaway and those in the group that had breastfeeding support alone, or had an operation later. After six months, mothers are contacted again to see if they are still breastfeeding.

What are the possible benefits and risks of participating?
The findings will help guide care for women and their babies who are trying to breastfeed in the future. There are some risks associated with the frenotomy procedure. These include bleeding, a small risk of infection, and a small risk of salivary duct damage. However, both breastfeeding support and the frenotomy are standard care practices. Therefore the researchers do not believe there are any additional risks as a result of taking part in this study.

Where is the study run from?
The study is co-ordinated from the National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU), based at the University of Oxford. Participants will be recruited from around 22 hospitals throughout the UK.

When is the study starting and how long is it expected to run for?
April 2018 to May 2021

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (UK)

Who is the main contact?
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Study website
www.npeu.ox.ac.uk/frosttie

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
38654; HTA 16/143/01

Study information

Scientific Title
FROSTTIE: A randomised controlled trial of FRenotomy and breastfeeding support Or breastfeeding Support without frenotomy to investigate continuation of breastfeeding for babies with Tongue-TIE

Acronym
FROSTTIE

Study objectives
To investigate whether frenotomy is clinically and cost effective to promote continuation of breastfeeding at three months in infants with breastfeeding difficulties diagnosed with tongue-tie.

Ethics approval required

Old ethics approval format

Ethics approval(s)
South Central - Oxford B Research Ethics Committee, The Health Research Authority, Whitefriars, Level 3, Block B, Lewin's Mead, Bristol, BS1 2NT, Tel: +44 (0)207 1048058, Email: nrescommittee.southcentral-oxfordb@nhs.net, 10/12/2018, REC ref: 18/SC/0580

Study design
Randomised; Interventional; Design type: Treatment, Process of Care, Management of Care, Surgery

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Tongue-tie

Interventions
The infants entered into the trial will be randomised 1:1 to either:
1. Frenotomy with standard breastfeeding support (intervention arm)
2. No frenotomy with standard breastfeeding support (comparator arm)

Intervention arm:
Infants who are eligible for the trial and whose parents consent for them to participate and who are randomised to frenotomy with breastfeeding support will undergo the procedure according to usual hospital practice. Frenotomy will be carried out by the usual trained practitioner for participating hospitals using their normal technique. Frenotomy is usually a quick procedure in which the tongue is lifted and the frenulum (the tissue between the underside of the tongue and the base of the mouth) is divided. Breastfeeding may be conducted immediately post-procedure, and the baby will undergo an immediate post-frenotomy observed feed. Parents will receive further advice on positioning and attachment together with standard post-frenotomy advice concerning bleeding and other post-frenotomy adverse events. Parents will be provided with details about how to access rapid breastfeeding support in the event of ongoing feeding difficulties and an appointment for at least one follow-up visit.

Previous comparator arm:
Infants who are eligible for the trial and whose parents consent for them to participate and who are randomised to breastfeeding support only will not undergo frenotomy, but at the frenotomy

clinic will undergo an immediate observed feed and will receive further advice on positioning and attachment together with standard post-frenotomy advice concerning bleeding and other post-frenotomy adverse events. Parents will be provided with details about how to access rapid breastfeeding support in the event of ongoing feeding difficulties and an appointment for at least one follow-up visit.

Current comparator arm as of 16/09/2019 (amended with protocol dated 28/06/2019):
Infants who are eligible for the trial and whose parents consent for them to participate and who are randomised to breastfeeding support only will not undergo frenotomy. Parents will be provided with details about how to access rapid breastfeeding support in the event of ongoing feeding difficulties and an appointment for at least one follow-up visit.

The study will compare how many babies are still breastfeeding at aged 3 months in the two groups, and will also look at the level of breastfeeding, the support provided, any further surgery on the tongue-tie and the mother's quality of life and perceptions of the level of breastfeeding of their baby. Information will be collected from the medical records by the clinical research team at the feeding support hospitals. The trialists will also ask the mothers to complete short questionnaires through a secure web-based data collection platform, or by post or phone if preferred.

Intervention Type
Mixed

Primary outcome measure
Any breastmilk feeding at 3 months according to maternal self-report, defined as any breastmilk feeding in the 24 hours prior to the infant reaching three months of age. A positive response is indicative of continuation of breastfeeding.

Secondary outcome measures
Measured by specific question unless noted, at first follow-up visit and 3 months of age:
1. Mother's pain while feeding during the previous 24 hours
2. Exclusive breastmilk feeding
3. Exclusive direct breastfeeding
4. Frenotomy in comparator group
5. Repeat frenotomy
6. Bleeding (following frenotomy or frenulum tear)
7. Post-procedure adverse events (tongue cut, scarring, salivary duct damage)
8. Maternal anxiety and depression dimension of EQ-5D-5L
9. Maternal health-related quality of life measured using EQ-5D-5L

Measured by specific question unless noted, at 3 months of age:
1. Mother's breastfeeding self-efficacy, measured using Breastfeeding Self-Efficacy Scale – Short Form
2. Amount of breastfeeding support used, measured by total number of contacts with any breastfeeding supporter since the FROSTTIE procedure (whether face to face, or by telephone)
Updated 16/09/2019 (amended with protocol dated 28/06/2019): Amount of breastfeeding support used, measured by total number of contacts with any breastfeeding supporter since the infant joined the trial (whether face to face, or by telephone)
3. Infant weight gain from birth
4. Infant post-randomisation weight gain
5. Age of child when s/he last received breastmilk

6. Time spent breastfeeding in previous 24 hours
7. Maternal health-related quality of life, measured using EQ-5D-5L
8. Maternal and infant NHS healthcare resource use

Measured by specific question at 6 months:
1. Any breastmilk feeding

Overall study start date
01/04/2018

Completion date
13/05/2021

Eligibility

Key inclusion criteria
1. Infant aged less than 10 weeks referred (by parent or other breastfeeding support service) to an infant feeding service with breastfeeding difficulties and judged to have tongue-tie
2. Parent has given informed consent for participation

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Planned Sample Size: 870; UK Sample Size: 870

Total final enrolment
169

Key exclusion criteria
1. Infants who have breastfeeding difficulties but are not judged to have tongue-tie
2. Babies born at less than 34 weeks' gestation
3. Babies with a congenital anomaly known to interfere with breastfeeding e.g. cleft palate, Down syndrome
4. Babies with a known bleeding diathesis
Added 16/09/2019 (amended with protocol dated 25/03/2019): 5. Infant has had a frenotomy prior to recruitment

Date of first enrolment
01/01/2019

Date of final enrolment
27/11/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Study participating centre
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
George Eliot Hospital
College Street
Nuneaton
United Kingdom
CV10 7DJ

Study participating centre
Homerton University Hospital
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
East Lancashire Hospital NHS Trust
Burnley General Teaching Hospital
Casterton Avenue
Burnley
United Kingdom
BB10 2PQ

Study participating centre

Great Western Hospital
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
The Cumberland Infirmary
Infirmary Street
Carlisle
Cumbria
United Kingdom
CA2 7HY

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
University Hospital of North Durham
North Road

Durham
United Kingdom
DH1 5TW

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre
Royal Manchester Children's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Sponsor information

Organisation
University of Oxford

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/143/01

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 13/03/2020:
The protocol and other study documents will be made available on the website https://www.npeu.ox.ac.uk/frosttie

The trialists will submit for publication in a high impact peer-reviewed journal. They aim to present findings to academic and professional audiences at key conferences. They will also bring the trial results to the attention of the Cochrane review authors so that they may be considered for inclusion in an updated review. The triallists will also submit the protocol for publication.

It is NPEU policy to send results to all trial participants, unless they have opted out. The trialists will also share the results with other breastfeeding mothers through national organisations working to support breastfeeding, appropriate websites, social and traditional media as well as with organisations designing services and guidelines about breastfeeding and tongue-tie to help make sure that the services provided in the NHS are based on what they have found.

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
A statement on the management of participant data sharing can be found at https://npeu.ox.ac.uk/ctu/privacy-notice

Previous publication and dissemination plan:
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IPD sharing statement
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v5	29/07/2020	06/01/2021	No	No
HRA research summary			28/06/2023	No	No
Results article		25/07/2023	26/07/2023	Yes	No