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Tongue tie and frenotomy: a feasibility randomised controlled trial

Submission date
20/10/2011

Recruitment status
No longer recruiting

Registration date
20/10/2011

Overall study status
Completed

Last Edited
28/11/2013

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Babies are sometimes born with a tongue tie. This is where the flesh which holds the tongue to the floor of the mouth, underneath the tongue, is too tight or too long and hence the baby cannot move the tongue as much as a normal baby. It is said that up to 3% of babies are affected i.e. a lot of babies.
It is possible to snip the tongue tied tissue (called the frenulum) and release the tongue tie. Recently this has become a spreading practice across different places in the UK. The reason this is done is that by releasing the tongue, the affected baby can breast feed more easily as able to latch onto the mothers breast without causing pain to the mother or irritation and failure of breast feeding.
We are conducting a study which will attempt to determine a way of measuring tongue tied babies, assessing their breast feeding, and if deemed to be tongue tied just after birth, the Mum will be invited to join our study. It is uncertain if cutting the tongue tie (called frenotomy) really does result in better breast feeding and also sustained breast feeding. Previous research has not been conclusive and that is why an initial study is required.

Who can participate?
100 babies and their Mums in the first few weeks after birth. If a baby is assessed to have severe tongue tie, they will not be invited to participate. We will not involve premature or other babies needing ongoing in patient medical care. Only mature term babies will be invited (via their Mums!) to be involved.

What does the study involve?
If the Mums agree to participate they will be randomly allocated to either immediate tongue tie treatment or a delay of 5 days whereby standard breast feeding advice /support will be given. If the infant is still struggling to feed, tongue tie release will be done on the other half of the group (i.e. 50 babies) at day 5 after study entry. Some babies at that point could be feeding well without that help.
Assessments will look at breast feeding competency including a questionnaire filled in by the Mums after the tongue tie treatment.

What are the possible benefits and risks of participating?
Frenotomy is a simple procedure done by a trained midwife and causes minimal discomfort to the baby.
If we find that we can involve 100 Mums and their babies over this time frame and our measures of assessment prove reliable and useful, a larger study will be run. If we show that tongue tie treatment genuinely benefits breast feeding babies, it would make a case for every district to offer this service.

Where is the study run from?
The study is carried out in Southmead Hospital Bristol, UK.

When is study starting and how long is it expected to run for?
October 2011 to October 2012.

Who is funding the study?
National Institure for Health Research (NIHR), UK

Who is the main contact?
Dr Sutcliffe
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10588

Study information

Scientific Title
A feasibility study for a randomised controlled trial to measure the impact of frenotomy in breastfed infants with tongue tie

Study objectives
A pilot study involving infants in their first few weeks of life whose mothers experience difficulty in breast feeding thought to be due to Tongue Tie.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 11/SW/0087

Study design
Interventional, treatment, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Paediatrics

Interventions
These babies will be randomised to Frenotomy (incision of the frenulum of the tongue in a tongue tied infant) at day 0 or day 5. They will be assessed using the LATCH tool (primary outcome). The Hazelbaker tool for tongue tie severity and reassessed at day 5.
Those randomised to delayed frenotomy will be given standard breast feeding support.
The main aim of the feasibility study is to establish if Mothers are willing to participate and complete the protcol. this will be a single blind assessment in which a person unaware of frentomy status will do the LATCH and other assessments.
Follow Up Length: 2 month(s); Study Entry: Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
LATCH score, measured pre and post frenotomy

Secondary outcome measures
1. Bresat feeding duration measured 8 weeks post procedure
2. HASLIFF score measured pre and post frenotomy
3. Maternal pain on breast feeding Likert scale measured pre and post frenotomy

Overall study start date
03/10/2011

Completion date
02/10/2012

Eligibility

Key inclusion criteria
1. Term born infants with a functionally significant tongue tie (Hazelbaker Assessment Tool for Lingual Frenulum Function [HATLFF] score between 6-12) with breast feeding difficulties (LATCH score <-8)
2. Male and female participants
3. Upper Age Limit is 14 days

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100; Description: This is a feasibility study which would determine sample size for a main study.

Key exclusion criteria
1. Preterm infants
2. Infants with serious congenital anomalies
3. Infants who have lost >10% of their birth weight unless found to be well enough after checking by a neonatologist
4. Infants with a HATLFF score of <6, and those over 2 weeks old will be excluded from the study
5. Mothers who do not want their baby to have surgery
6. Babies that have not received vitamin K soon after birth, unless the mother agrees to an injection of vitamin K one hour before entering the trial

Date of first enrolment

03/10/2011

Date of final enrolment
02/10/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Child Health
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
Southmead Hospital (UK)

Sponsor details
Southmead Road
Westbury-On-Trym
Bristol
England
United Kingdom
BS10 5NB

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/find_us/southmead_hospital.aspx

ROR
https://ror.org/05d576879

Funder(s)

Funder type

Government

Funder Name
National Institure for Health Research (NIHR) - Research for Patient Benefit (RfPB)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2014		Yes	No