

# A trial of tongue-tie division and its immediate effect on breastfeeding

<b>Submission date</b> 22/06/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/07/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/09/2015	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Ankyloglossia, more commonly known as “tongue-tie”, is a common congenital (present from birth) condition which affects the way the tongue moves in the mouth. About 4% of children are born with this problem, in which the cord-like skin (frenulum) that joins the bottom of the tongue to the floor of the mouth is too short, limiting the tongue’s range of movement. In some cases, babies may have difficulties breastfeeding, as they are unable to open their mouths wide enough or to suck properly. This can lead to painful nipples for the mother, and can mean that the baby does not gain weight as it should. If feeding is affected, then a tongue-tie division procedure is recommended. This simple operation involves cutting the frenulum to allow the tongue to move. Tongue-tie division is often carried out when the child is a few months old, and afterwards the baby is able to feed normally straight away. It has been suggested that the fact that mothers report an immediate improvement in breastfeeding could be down to the placebo effect (that it works only because it is expected to). The aim of this study is to investigate the possibility that the reported improvements in breastfeeding are due to the placebo effect.

### Who can participate?

Babies under four months of age with tongue-tie, who have difficulties with breastfeeding.

### What does the study involve?

Participants are randomly allocated into two groups. Those in the first group receive the tongue-tie division procedure, and those in the second group did not receive the procedure. All infants are returned to their mothers with a square of gauze under their tongues so that the mothers do not know whether their child has had the procedure or not. Before and after the procedure, mothers are asked to feed their babies and to give their opinions on how well their child is feeding, and their level of pain.

### What are the possible benefits and risks of participating?

Not provided at time of registration.

### Where is the study run from?

Wessex Regional Centre for Paediatric Surgery (UK)

When is the study starting and how long is it expected to run for?  
October 2003 to July 2004

Who is funding the study?  
Southampton University Hospitals NHS Trust (UK)

Who is the main contact?  
Mr Mervyn Griffiths

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr Mervyn Griffiths

**Contact details**  
Wessex Regional Centre for Paediatric Surgery  
Southampton General Hospital  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
120/01/t

## Study information

**Scientific Title**  
A double-blind, randomised, controlled trial of tongue-tie division and its immediate effect on breastfeeding

**Study objectives**  
That division of tongue-tie causes an immediate change in breastfeeding which the mother can detect and is not due to placebo effect

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

**Study design**

Single centre double-blind randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Tongue-tie

**Interventions**

1. Both participants & the observer were blinded to the intervention
2. Tongue-tie division and non-division
3. Unblinded follow up at 1 day & 3 months

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Subjective and objective change in breastfeeding
2. Maternal pain score

**Secondary outcome measures**

1. Subjective changes in breastfeeding
2. Breastfeeding rates
3. Complications and acceptability of procedure to parents

**Overall study start date**

30/10/2003

**Completion date**

31/07/2004

# Eligibility

## Key inclusion criteria

1. Less than 4 months of age
2. Tongue-tie present
3. Symptomatic of breastfeeding problem

## Participant type(s)

Patient

## Age group

Child

## Upper age limit

4 Months

## Sex

Both

## Target number of participants

60

## Key exclusion criteria

Does not meet inclusion criteria

## Date of first enrolment

30/10/2003

## Date of final enrolment

31/07/2004

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Wessex Regional Centre for Paediatric Surgery**

Southampton

United Kingdom

SO16 6YD

# Sponsor information

**Organisation**

Southampton University Hospitals NHS Trust (UK)

**Sponsor details**

Southampton General Hospital  
Tremona Road  
Southampton  
England  
United Kingdom  
SO16 6YD

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.suht.nhs.uk/home.aspx>

**ROR**

<https://ror.org/0485axj58>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Southampton University Hospitals NHS Trust (UK)

**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?
<a href="#">Results article</a>	results	01/06/2012		Yes	No

