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

Recruitment status	<ul><li>Prospectively registered</li></ul>		
No longer recruiting	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting  Overall study status  Completed		

#### 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 tonguetie 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 Hopital Tremona Road Southampton United Kingdom SO16 6YD

# Additional identifiers

#### Protocol serial number

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)

Southampton and South West Hampshire Local Research Ethics Committees, 6 November 2003 ref: 120/01/t

## Study design

Single centre double-blind randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Quality of life

#### 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(s)

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

#### Key secondary outcome(s))

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

## 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** 

#### Healthy volunteers allowed

No

#### Age group

Child

#### Upper age limit

4 months

#### Sex

All

#### 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

United Kingdom

England

## Study participating centre

Wessex Regional Centre for Paediatric Surgery

Southampton United Kingdom SO16 6YD

# Sponsor information

### Organisation

Southampton University Hospitals NHS Trust (UK)

#### **ROR**

https://ror.org/0485axj58

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

Southampton University Hospitals NHS Trust (UK)

# **Results and Publications**

# 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	01/06/2012	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes