

## Timing Of Primary Surgery (TOPS) For Cleft Palate: A Randomised Controlled Trial



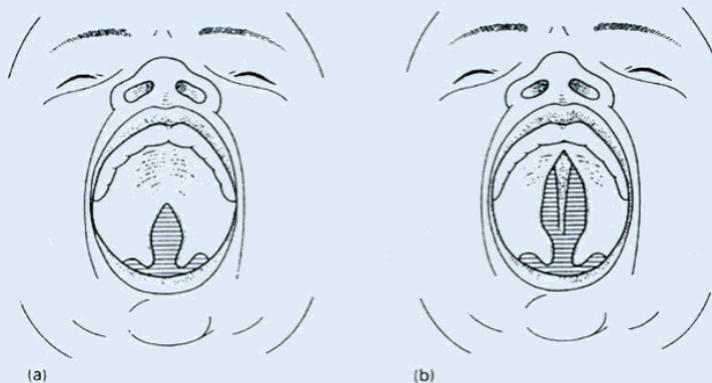
**This is a summary of the main results of a clinical study to find out whether a baby born with a cleft palate should have their surgical repair at 6 or 12 months of age.**

### *Thank you!*

We thank all the children and their parents and carers who took part in the TOPS trial; the staff of all participating centres; and the research teams assisting with the trial throughout.

### *Why was the research needed?*

A cleft palate happens when the structures that form the palate fail to join together when a baby is developing in the womb. This cleft in the palate leaves an opening between the roof of the mouth and the nose when the baby is born. The drawings below show (a) a cleft involving the soft palate and (b) a cleft involving the soft and hard palate.



Babies born with a cleft palate may have difficulty with feeding. They may also have hearing, dental and speech problems. Most of these problems improve after surgery and with help such as speech and language therapy.

Babies with cleft palate can have their surgery at different times, usually before 18 months of age. One question that has remained unanswered for many years is when is the best age to have the surgery.

Some surgeons repair a cleft palate when the baby is around 6 months of age, others when the baby is around 12 months. The age of surgery could affect speech, facial growth and safety of the surgical procedure. There is no reliable evidence to help surgeons decide whether one timing is better than another. The only way to find out is to compare the outcomes from babies receiving their surgery at the different times.

### *What were the main questions studied?*

The TOPS trial aimed to find out whether the best possible speech outcomes were achieved by cleft palate repair at 6 or 12 months of age. We also wanted to understand if the age at surgery was related to differences in hearing, facial growth or safety.

## *Who carried out the research?*

The TOPS trial was planned by an international group of cleft specialists and researchers across Europe (Denmark, Norway, Sweden and the United Kingdom) and South America (Brazil). TOPS was funded by the National Institute of Dental and Craniofacial Research in the USA and sponsored by the University of Manchester. Ethics committees in each country approved the trial protocol.

Data were sent to researchers at the University of Liverpool for monitoring and analysis. Anonymised data sharing requests may be made to [lctc@liverpool.ac.uk](mailto:lctc@liverpool.ac.uk)

## *Who participated in the study?*

Babies born with a cleft palate that did not involve the lip were eligible to take part in TOPS. The baby needed to be considered medically fit for surgery at 6 months old.

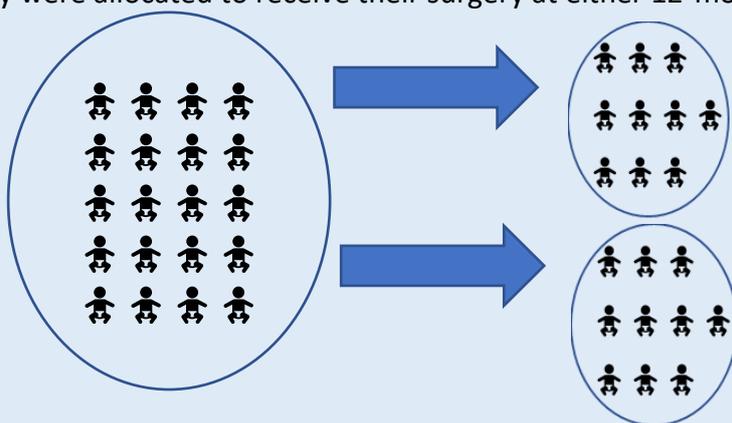
A total of 558 babies were recruited from 23 specialised cleft treatment centres between September 2010 and July 2015

## *What treatments or interventions did the participants take/receive?*

Babies in TOPS received surgical repair for their cleft palate at either 6-months or 12-months of age. All babies received the same surgical technique to repair the cleft.

## *What happened during the study?*

Babies born with a cleft palate were invited to take part in the trial. If their parent/carer gave consent then they were allocated to receive their surgery at either 12-months or 6-months of age.



The age group that each baby was allocated to was decided at random using a computer system. In TOPS babies had an equal chance of being in either of the two groups. This process means that if one group does better than the other, we can be confident it was likely due to the age at surgery and not because of other differences between the groups.

The main study outcome was velopharyngeal insufficiency (VPI) at age five years. VPI happens when the soft palate does not close tightly between the mouth and the nose during speech. This causes air to escape from the nose during speech and causes difficulties in producing specific speech sounds. Preventing this is a main purpose of surgery.

Video and audio recordings were made of each child's speech assessments at 12 months, 3 years and 5 years of age. These recordings were assessed by trained speech and language therapists who did not

know whether the babies received their surgery at 6 or 12 months of age. Hearing and middle ear function were also assessed at the same time points. Growth was measured at 12 months and facial growth/development was assessed at age 5 years using dental impressions and photographs. Safety of the surgeries were also assessed.

## *What were the results of the study?*

235 out of 281 (84%) babies allocated to receive their surgery at 6 months stayed in the study until their age 5-year assessments and provided video and audio recordings of their speech assessments.

In the group allocated to receive their surgery at 12-months this was 226 out of 277 (82%).

Velopharyngeal insufficiency (speaking through the nose) was observed less frequently in the 6-month than the 12-month age-group. This indicates a decrease in the risk of speech problems caused by air escaping from the nose during speech when babies receive their surgery at the earlier age.

There were 3 serious adverse events in the 6-month group and 1 in the 12-month group. All were resolved at follow up. Other safety events were uncommon and similar between groups.

At 12 months, hearing and middle ear function were poorer in the group awaiting surgery. These differences were not seen at ages 3 and 5. This suggests the benefit of earlier operation is not sustained.

There were no clear differences between groups for growth at 12 months. Jaw and facial growth outcomes measured at 5 years indicated poorer outcome for the 6-month group. The difference between the two groups was not thought to be clinically meaningful.

## *How has this study helped patients and researchers?*

This is the largest randomised controlled trial evaluating the effect of the timing of surgery on study speech outcomes.

TOPS was carried out in specialist centres that provide care and surgical repair of many babies born with a cleft palate.

The trial results support carrying out palate repair at 6 months in centres with adequate facilities and staff to ensure safe surgery in infants.

## *Details of any further research planned*

The results overall show that surgery at 6-months of age led to better speech outcomes than surgery at 12-months. However, there were some variation within the countries that took part.

Further research will include using the data to explore this in more detail.

## *Where can I learn more about this study?*

LCTC will publish the results of the TOPS trial in a medical journal.

The trial publications will not disclose the identity of any of the babies that took part in TOPS.

If you would like to find out more about the trial and the publications then please visit

<https://lctc.org.uk/research/tops/>