



# Timing Of Primary Surgery for Cleft Palate NEWSLETTER

June 2011, Issue 6

## New Trial Coordinator at the DCC

Lea Bradshaw joined the TOPS team at the Data Coordinating Centre, University of Liverpool on the 1st May 2012.



Lea has a background in life sciences and has previously been involved in small clinical trials. Lea will be your main contact in the Data Coordinating Centre, from where she will help coordinate TOPS.

Lea can be contacted at the Data Coordinating Centre University of Liverpool  
Telephone: +44(0) 151 282 4727  
Facsimile: +44(0) 151 282 4721  
Email: [tops.trial@liv.ac.uk](mailto:tops.trial@liv.ac.uk)

## In this issue

1. TOPS trial coordination at the DCC
2. TOPS recruitment update and TOPS100th Patient!
3. Speech inclusion criteria
4. Congratulations Gunvor!
5. TOPS cover during July and August
6. Frequently asked questions
  - Randomisation
  - Participant withdrawal

## TOPS Recruitment Update

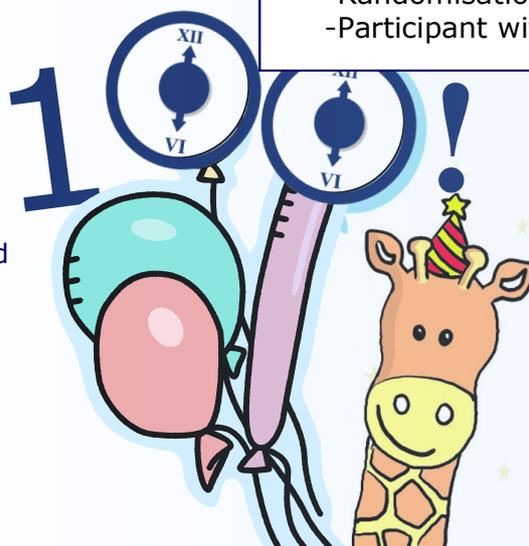
**135** participants have now been randomised into the TOPS trial.

May was a record month with 18 babies randomised to the trial.

Congratulations to the team in Bauru who recruited the 100th participant to the TOPS trial and who will soon receive a small prize in the post.

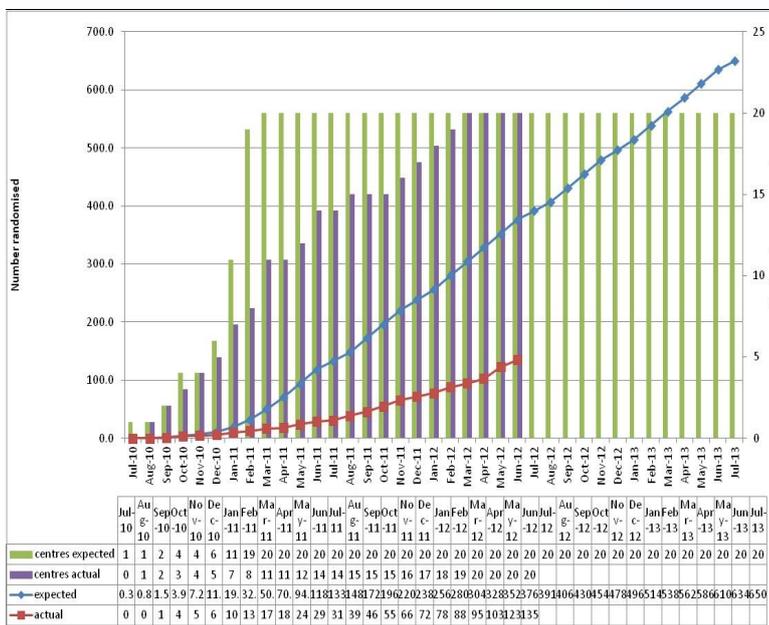
Congratulations also to the team in Copenhagen who recruited their first three patients to TOPS in May 2012.

Keep up the great work!



## Recruitment Graph– 25-06-2012

650



135

The next meeting of the TOPS Trial Steering Committee will be on the 12th July 2012

The next meeting of the Data and Safety Monitoring board will take place on the 4th September 2012



## TOPS Inclusion/Exclusion criteria

One of the TOPS inclusion/exclusion criteria concerns the languages spoken at home. Here we would like to clarify this criterion, in order to help you decide about the inclusion of patients.

These language criteria have been included to ensure appropriate speech assessments of the TOPS children.

The inclusion criteria states:

**"Is one parent/carer a native language speaker of the majority language in the country of residence?"** and this should be interpreted as one parent or carer who has their first/primary language as the majority language of the country.

The language spoken at home should also be the main language of the country. Although more than one language may be spoken at home the main language should be the majority language of the country of residence.

For example,

In a family living in the UK the mother speaks English as her primary language but she was raised in Spain. Both the mother and father speak Spanish to the child but mostly speak in English. This baby should be recruited to the trial

## TOPS Frequently asked questions

**Q. The Randomisation System has given an error message, what should I do?**

**A. Please note the details of an error message and if possible save the screen shot of the message. Get in touch with the Data Coordinating Centre as soon as possible so we can investigate the source of the problem and help you randomise the patient.**

**Q. After randomisation the family have decided that they do not want the allocated timing of surgery. Should they be followed up?**

**A. Unless the parents explicitly withdraw from the follow-up portion of the trial, the centres should continue the follow-up for the duration of the trial.**

## Gunvor receives Norwegian Royal Award

Gunvor Semb has been awarded the 'Commander of the Royal Norwegian Order of St Olav'. Gunvor attended a ceremony in Norway on the 8 March 2012 where she received her award and will be received by King Harald of Norway at the Royal Palace on the 31st August 2012.



*'a reward for distinguished services rendered to the country and mankind'*

The award is one of the highest honours that any civilian can ever receive in her home country of Norway. We would like to congratulate Gunvor on behalf of the TOPS trial.

## TOPS Cover July & August

During July and August staff at the Data Coordinating Centre will be taking holidays.

For urgent queries to the Data Coordinating Centre between 13-07-2012 and 23-07-2012, please the Administrative Centre who will be bale to help or to direct your query.

### UK Bank Holidays

27th August—Offices at the AC and DCC closed.

**We hope you all have a TOPS summer!**



## TOPS Contact Details

### Main Contact Administrative Centre

Dieter Weichart (Project Manager)  
Tel: +44 (0) 161 275 6792  
Email: [d.weichart@manchester.ac.uk](mailto:d.weichart@manchester.ac.uk)

### Main contact at the Data Coordinating Centre

Lea Bradshaw (TOPS Trial Coordinator)  
Tel +44 (0) 151 282 4727  
Email: [tops.trial@liv.ac.uk](mailto:tops.trial@liv.ac.uk)

