

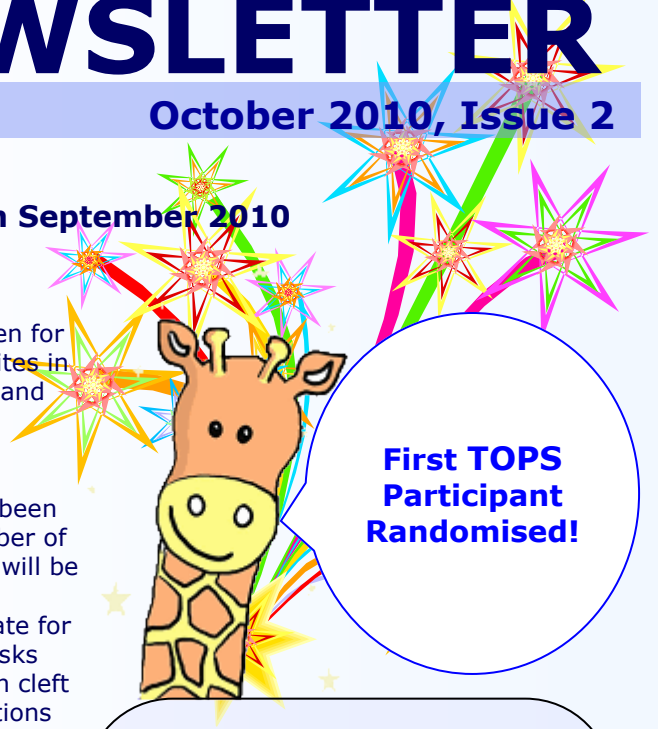
TOPS First Participant Randomised

First TOPS participant randomised on the 10th September 2010

Congratulations to the TOPS team at Central Manchester University Hospitals NHS Foundation trust who randomised the first TOPS participant on the 10th September 2010. Congratulations also to the team at Alder Hey Children's NHS Foundation trust who randomised their first participant on the 28th September 2010.

First participant randomised to the TOPS trial!

Sites at Manchester, Liverpool, Leeds and Glasgow are now open for recruitment. Other sites in the UK, Scandinavia and Brazil will open for recruitment over the coming months. Site initiation visits have been scheduled for a number of sites and other sites will be contacted shortly to arrange a suitable date for a visit when TOPS tasks will be discussed with cleft teams and any questions answered.



First TOPS Participant Randomised!

TOPS Protocol Amendment

Minor amendments to the TOPS protocol, current version 2.1 06-September-2010

The TOPS protocol has been amended to version 2.1 (date). In the UK this amendments meets the definition of non-substantial requiring only notification to the ethics committee. This protocol will be used for the ethics applications in Scandinavia and Brazil.

An electronic version of the protocol has been sent to sites. Sites who already have their site file will receive a hard copy by post together with instruction on where to file.

Sites who have not yet received their investigator site file will receive this fully up to date with the protocol and trial specific documents.

At or shortly before the site visit each site will receive their investigator site file, participant packs including Case Report Forms, printed copies of information sheets and consent forms and any other documentation/equipment needed.

Important Dates

**TOPS Trial Steering Committee
15th
November
2010**

Good Clinical Practice training – reminder on how to complete

- Attending a course run by your institution (please ask us for a Good Clinical Practice attendance log form if certificates are unavailable).

For International sites:

- Completing the National Institute of Health online Good Clinical Practice training free of charge (for international sites). <http://phrp.nihtraining.com/users/login.php>

For UK sites

- In the UK only—completing the National Institute of Health Research (NIHR) Clinical research Network (CRN) online Good Clinical Practice training free of charge. <http://www.crncc.nihr.ac.uk/training/courses/gcp>

Main Contact Administrative Centre

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

Main contact at the Data Coordinating Centre

Nicola Harman (Trial Coordinator)
Tel +44 (0) 151 282 4727
Email: n.harman@liv.ac.uk

If you have an queries regarding the TOPS trial or would just like to get in touch please contact a member of the TOPS trial team at the Administrative or Data Coordinating Centre: