



Issue 08

Autumn edition – October 2012

Hello to all our eTHoS trial sites, established and new!

Welcome to the eighth eTHoS study newsletter.

Recruitment to date

We have currently randomised 341 participants into the eTHoS trial!

Twenty-nine sites are open to randomise participants as of this month. The top recruiting site is still Mr Malcolm Loudon's team at Aberdeen Royal Infirmary with a grand total of 70 patients randomised to date – fantastic work! **Mr Madan Jha** at James Cook University Hospital in Middlesbrough remains the top recruiting site in England with 36 participants (see page 2 for further details).

Since the last newsletter, recruitment has started at Mr Suresh Pillai's site at Lincoln County Hospital; Mr Graham Sunderland's site at Southern General Hospital, Glasgow; and Mr Matthew Tutton's site at Colchester General Hospital. **Congratulations!**

We need everyone's continued help to make the eTHoS trial a success - please let the study office know if there is anything we can do to support you further.

*The eTHoS Recruitment table is shown on page 2
Winners of July/Aug competition are announced on page 3
Recent document changes are summarised on page 4
Competition and announcements on page 5*

Get ready to celebrate!



We are nearing the half-way milestone for eTHoS!

In order to celebrate reaching this milestone in style, the eTHoS study CI, Prof Angus Watson, has promised the site which randomises participant number 400 a bottle of sparkling!

Only another 60 participants to go! To help you keep track, watch the countdown on the eTHoS website (study news page).

Also, **everybody** will get a special, also with sparkle, eTHoS surprise to mark the occasion, so make sure we know about all eTHoS staff at your site.



Remember to invoice CHaRT regularly for the participants your site has randomised.

eTHoS Randomisations by Site Table

Principal Investigator and site	Recruits
Mr Malcolm Loudon: Aberdeen Royal Infirmary	70
Prof Angus Watson: Raigmore Hospital, Inverness	40
Mr Madan Jha: James Cook University Hospital	36
Mr Marc Lamah: Royal Sussex Hospital, Brighton	35
Mr Anil Agarwal: University Hospital of North Tees	27
Mr Venkat Shanmugam: Darlington & Durham NHS Trust	22
Mr Muti Abulafi: Croydon University Hospital	17
Mr Yasser Mohsen: Hillingdon Hospital	14
Mr Suhail Anwar: Huddersfield Royal Infirmary	9
Mr Bill Speake: Derby City Hospital	9
Mr Steve Brown: Northern General Hospital - Sheffield	8
Mr Finlay Curran: Manchester Royal Infirmary	7
Mr Ponnandai Arumugam: Royal Cornwall Hospital, Truro	7
Prof Paris Tekkis: Chelsea and Westminster Hospital	6
Mr Euan MacDonald: Forth Valley Royal Hospital, Stirling	6
Mr Ian Lindsey: John Radcliffe Hospital, Oxford	5
Mr Harjeet Narula: Pinderfields Hospital, Wakefield	4
Mr Sandeep Kapur: Norfolk and Norwich University Hospital	4
Mr Ramesh Rajagopal: Glan Clwyd Hospital, Rhyl	3
Mr Liviu Titu: Wirral University Teaching Hospital	3
Mr Mark Mercer-Jones: Queen Elizabeth Hospital, Gateshead	3
Mr Ray Delicata: Nevill Hall Hospital, Abergavenny	3
Mr Alan Grant: Dr Gray's Hospital, Elgin	1
Prof David Jayne: Leeds General Infirmary	1
Mr Reuben West: Weston Hospital	1
Total	341



And the winners are...



July and August were competition months (any site which randomised two or more participants was entered in a draw for a voucher).

Claire Cochrane, one of the CHaRT trial managers, acted as the independent 'lucky fairy' for the occasion, while Jackie oversaw the proceedings.

On the left (from left to right): Claire Cochran ('lucky fairy'), Jackie Ellington and Hanne Bruhn in CHaRT, Aberdeen.

Congratulations!

Drum roll* *Drum roll* *Drum roll* *Drum roll

– the winner of the draw was site number 40 - **Royal Cornwall Hospital**, many congratulations!

On the right: Having done the deed – Claire showing the lucky site number (40).



On the left: Alyson Andrew and Kirsty Bond proudly holding their prize.



Kirsty Bond's response on being informed that their site had won declared "Wow! Many thanks! The last time I won anything was when I came 3rd in the bunny-hop race when I was about 7!!". The lucky fairy clearly found a deserving winner of the eTHoS recruitment prize!

You snooze, you lose



Remember to invoice CHaRT regularly for the participants your site has randomised.

You need to claim your payment before the end of the trial, otherwise CHaRT will not be able to pay for randomised participants.

Our most recent site visit – Glasgow



Right: Consultant Colorectal Surgeon, Mr Graham Sunderland at Southern Sunderland at Southern General Hospital, Glasgow, has joined eTHoS as a new PI.



Left (left to right): Joanne Mangan, Hanne Bruhn and Katherine McGuigan at a recent site visit in Glasgow. Kathleen MacLeod acted as the photographer.

Recent document changes summarised

Please note that we have received a correction from REC regarding numbering of amendments. Amendment 8 is now number 9 and amendment 8 does not exist for eTHoS. Please see eTHoS website for details (note to file) and update the site folder accordingly.

Ethical amendments number 10 & 11 (non substantial) have been approved by ethics and R&D offices.

Amendment 10 summarised:

Baseline Case Report Form (BCRF) - (now version 3.3 June 2012)

- Section 'Best Contact Details'- added an explanatory note of the purpose of 'Best contact' .
- Section 'Randomisation Information - Exclusion criteria' have been clarified.
- Section 'Randomisation Information', reminder of what is needed for randomisation.

Details of Hospital admission and colorectal surgery - (now version 3.2 June 2012)

- Section 'Grade of operator' – corrected spelling.
- Section 'Intra-operative complications' added field 'yes/no'.

6 weeks Case Report Form (6wCRF) - (now version 3.3 June 2012)

- Section 'Date of visit' - added box for response if participant did not attend visit.
- Section 'Clinical appointment' – added box for responses of yes/no if 'Further clinical appoint required'.

eTHoS ineligible or declined form - (now version 3.1 June 2012)

- Section 'Q5 Reasons for non-inclusion' – have added HALO to exceptions; rephrased to 'Prior surgical treatment for anal sphincter injury repair'; re-phrased to 'known inflammatory bowel disease'; re-phrased and added 'malignant gastrointestinal disease, within the last 5 years'.

Serious Adverse Event/Death Report Form - (now version 1.1 June 2012)

- Section 'Patient Details' – changed 'patient' to 'participant'.
- Section 'Q1 Type of event' – Changed spelling of 'hospitalisation'.
- Re-phrasing of section to 'Assessment of whether the event resulted from administration of any of the research procedures'.
- Section 'Q7' re-phrasing to 'Is it reasonably likely that the adverse event resulted from administration of any of the procedures required by eTHoS?'.
- Section 'Q7a. Why?' has been deleted.

Amendment 11 summarised:

Participant Questionnaire 1 year - (now version 2.2 August 2012) and covering letter (now version 1.3 August 2012)

- Clarified that this questionnaire is posted to participants from CHaRT using the date the participant joined the study (not the operation date).

Participant Questionnaire 2 year - (now version 2.2 August 2012) and covering letter (now version 1.3 August 2012)

- As above.

Participant Questionnaire 5 year (now version 2.2 August 2012) and covering letter (now version 1.3 August 2012)

- As above.

All sites have been sent copies of the new documents including copies for the site file.

Please note that sites are not sent copies of covering letters.

Please contact Jackie (01224 438195) if you need more copies of the paperwork.

You will find all the new versions of these documents on the eTHoS website

<https://w3.abdn.ac.uk/hsru/Ethos/>





Hanne and Joy managed a flying visit to Norfolk and Norwich University Hospital to welcome Georgina Glister to the eTHoS team on 22nd August.

On the right (from left to right): Hanne Bruhn and Georgina Glister, the new lead surgical research nurse in Norfolk and Norwich. Joy Eldridge took the picture.



Study news: Update on device recall

Johnson and Johnson Endo surgery division recalled a batch of their PPH01 and PPH03 devices. This was due to a manufacturing issue with the firing mechanism. This followed a number of incomplete firings of the staple guns in a batch manufactured after November 2011.

A number of eTHoS sites were or have been affected by the recall and subsequent lack of stock. However, J&J have indicated that they expect full recovery by November 2012. Most eTHoS sites are back on track now.

If you were or still are affected please let Kathleen MacLeod know (kathleen.macleod3@nhs.net; tel.: 01463 255836), if you have not done so already, so sponsors and the funder can be updated. We may also be able to help you get stock if required.



Congratulations to James Cook, Middlesbrough

Congratulations to Mr Madan Jha and Research Nurse Marie Branch at James Cook University Hospital, Middlesbrough, who have met their recruitment target for eTHoS and continue recruiting. Thank you so much for your all your work for eTHoS!

December is a competition month

In order to be entered in to a draw for a £10 M&S voucher, your site simply has to randomise more eTHoS participants than were randomised by the site in December 2011.

Sites which have started recruiting after December 2011 will find this easy; you just have to randomise at least one participant in order to be entered in the draw!



Quiz - Answers



Q 1	The 'best contact' is used for...	b) A person to contact should the participant move house
Q 2	If a participant indicates a strong preference for Operation A or B in the Baseline Questionnaire, are they eligible to enter the trial?	a) Yes, as long as they still wish to take part in the trial and understand they will be randomised to a treatment
Q 3	If a participant receives another operation than either eTHoS options, should they remain on the trial?	b) Yes, all the information will be collected and used in the analyses
Q 4	What should ideally be done as close to surgery as possible?	d) All of the above [a) Randomisation; b) Hand participant their 1 week questionnaire; c) Enter weight and height data (taken within last 6 months)]
Q 5	What is a SAE in eTHoS?	b) They can be expected or unexpected and are events related to the surgery that causes death, is life threatening, requires hospitalisation, results in significant incapacity/ disability or is otherwise considered medically significant by the investigators.
Q 6	Data collection can start...	c) After informed consent has been given

And the winner of the quiz is...

The winner of the quiz, with all questions answered correctly, is Marie Branch from James Cook University Hospital, Middlesbrough.

On the right: Marie Branch, with her prize voucher – well done Marie!



On the left: Jackie Ellington on her recent holiday in the USA, next to a Halloween tree!

On the right: Hanne Bruhn wrapped up warm on her recent holiday in Iceland.



Wishing you continuing success with recruitment!

