



Latest News and Updates

Greetings

Welcome to the June 2010 issue of the HOLLT Study Newsletter.

As the HOLLT Study proceeds we have reached a significant milestone with the recruitment of our 36th patient in January. The recruitment of Ostrava's fourth patient enabled us to achieve this milestone of equalling the total number of cases reported in the landmark Bouachour study. However, there is still a long way to go before we reach the 250 patients required. Recruitment continues to be a challenge which can be addressed by the sites with enthusiastic recruitment and by the Coordinating Centre with continuing negotiations with potential sites.

Issue 4, June 2010



Hyperbaric Medicine Unit
Royal Hobart Hospital
Hobart, Australia
Hobart Staff enjoying the snow

Recruitment update

Participating Site		Patients
	Melbourne	14
	Graz	1
	Pilsen	2
	Ostrava	6
	Rome	2
	Stockholm	12
	Hobart	1
	Vancouver	-
	New Delhi	-
Total		38

With recruitment an ongoing challenge HOLLT continues to progress slowly. A total of 5 patients were recruited during 2009. The introduction of a Clinical Research Agreement to formalise the relationship between the sites and Monash University and provide a mechanism for making payment for the successful recruitment of patients has been partially responsible for this. Rather than advancing HOLLT, in many cases this has delayed the start-up of the study or stalled patient recruitment while lawyers negotiate the terms of the agreement. While some sites have successfully negotiated this difficulty it remains an obstacle for others which will hopefully soon be resolved.

Currently HOLLT has eight active sites with a total of 38 patients recruited. Recruitment is looking much better for 2010 with 5 patients already recruited, the most recent in March 2010. However, in order to reach our target of 250 patients, recruitment needs to increase substantially. The addition of two new sites, negotiations with further potential sites and the increase in the enrolment window from 24 to 48 hours post injury will go some way towards improving recruitment figures.

Melbourne, Rome, Graz and Stockholm have seen patients for their final, 24 month study visit and 22 patients have now reached this time point. Thanks to you all for your great efforts in following up patients in the HOLLT Study.

Remember, every potential patient at your site matters.

Contact Us

We welcome your questions, comments suggestions and contributions on any matter relating to the HOLLT Study. Please send your message to: hollt@monash.edu

Alternatively you can contact us on:

Phone: +61 3 9903 0926

Fax: +61 3 9076 3052

Website: www.hollt.org



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Updated documents

The HOLLT Protocol has been substantially re-arranged to improve readability and comply with GCP Guidelines. The section order has been numbered and reorganised and there are some changes to the original text, largely for the purpose of clarification, particularly the Entry and Exclusion Criteria. Sections have been added with the information provided previously available to collaborators in the HOLLT Study Manual.

The only significant study design change is an increase of the enrolment window from 24 to 48 hours post injury. We hope that this change will

make it easier to enrol patients into the HOLLT study.

The latest version of the HOLLT Protocol Version 8.0 dated 4 January 2010 can be found on the HOLLT website. Please notify your local ethics committee of the amended version if this is a requirement.

The latest version of all HOLLT Documents can be found on the HOLLT Website at www.hollt.org. They are located in the secure Collaborators area and you will need to log on with your user name and password to access them.

Study Promotion

In order to recruit successfully awareness of the HOLLT Study needs to be maintained with trauma surgeons, orthopaedic teams, anaesthetic departments and intensive care staff. It may be time to conduct a new advertising campaign revisiting the display of posters and finding opportunities to promote the HOLLT Study among colleagues. The poster and promotional slides have been updated to reflect the protocol revision. Please let me know if you would like a copy.



Welcome

We extend a welcome to the following sites who have joined the HOLLT collaboration and received ethics approval since the last newsletter:

- Dr David Harrison and his team at Vancouver General Hospital, Canada
- Dr Tarun Sahni and his team at Indraprastha Apollo Hospital, New Delhi, India

Hobart recruits their 1st patient into study!

Congratulations to Dr Susannah Sherlock and her team at the Royal Hobart Hospital, Australia for recruiting their first patient in February.

Change of Address

The HOLLT Coordinating Centre at Monash University has recently moved premises – just along the street to the next building. The new address is:

Department of Epidemiology & Preventive Medicine
School of Public Health and Preventive Medicine
Monash University
The Alfred Centre
99 Commercial Road
Melbourne Vic 3004

New email address

The HOLLT email address has also changed. The new email address is: HOLLT@monash.edu

The phone and fax numbers have not changed.