

ENCHANTED News

Enhanced Control of Hypertension and Thrombolysis Stroke Study

January 2013

Highest Recruiter Profile:

Yutian County Hospital, Hebei Province, China

PI Name: Wang Jinchao

PI Specialty: Neurology

Study Coordinator: Wang Lei



From left to right: Shi Lixia, Zhen Zhigang, Wang Liyan, Li Haijun, Wen Huixin, Zhang Sheng, Liu Changjie (President of hospital), Chen Wengang, Wang Jinchao (PI), Wang Lei, Chen Yuqin.

Number of beds in the hospital: 600

Number of ICU Neurology beds in the hospital: 11

Number of Stroke Cases in 2012: 1690

Date first patient randomised: 16th April 2012

Recruitment as of 17th January, 2013: 26 Patients



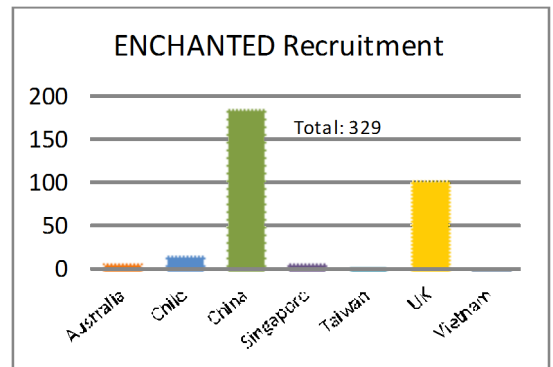
www.enchanted.org.au

Recruitment

The 300th patient was randomised at Royal Victoria Infirmary Hospital in the UK on the 18th of January 2013. Congratulations to the team, and to all our sites for the continual growth of recruitment in ENCHANTED!

In the last 11 months we have recruited a total of 329

patients into ENCHANTED. This global total includes 10 patients in Australia, 17 patients in Chile, 183 patients in China, 10 patients in Singapore, 6 patients in Taiwan, 102 patients in the UK and 1 patient in Vietnam, our newest country to recruit to ENCHANTED.



Meetings

The ENCHANTED team presents posters, presentations and publications at various local and international meetings around the world. In the last 6 months, there have been presentation in the UK, Brazil, USA and Thailand to name a few.

Investigator Meetings

Taiwan: During the Taiwan Stroke Society Quarter Meeting on 9th of Sept 2012, Professor Craig Anderson and Professor Tsonghai Lee updated the Taiwan investigators on ENCHANTED's progress. Taiwan's ENCHANTED Coordinator Chingyi Wang also ran a brief training session.

Korea: On 17th Nov 2012, Professor Craig Anderson and Professor Jong S. Kim did a pre-initiation study introduction to interested Korean investigators.

UK: On 5th Dec 2012 in conjunction with the UK Stroke Forum in Harrogate. Professor Tom Robinson and Professor Craig Anderson gave the UK investigators an update and informed the plan about the study.

Thailand: On 16th of Jan 2012, an Investigators meeting was held in Bangkok, in conjunction with the Thai Stroke Society Meeting. Professor Craig Anderson and Professor Nijasri Suwawela presented ENCHANTED and plans are to commence recruitment in Thailand in 2013

Presentations/ Posters

Tracy Kumar, the ENCHANTED Project Manager in the UK presented a poster at the South East Stroke Research Network (SESRN) Annual Meeting on the 16th November 2012.

Professor Pablo Lavados presented a poster at the World Stroke Congress in Brasilia, in October and at the International Symposium on Collaterals to the Brain in Los Angeles, USA in early November of last year.



THE GEORGE INSTITUTE
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Spotlight
on:



Informed Consent

Some of the most common audit findings during FDA inspections involve errors in the Informed Consent process of participants. Examples include:

1. Consent forms signed after treatment has commenced.
2. The wrong consent form signed by participant or person responsible/ legal representative.
3. Names, signatures & dates on the consent form are incomplete.

In order to prevent these errors in the ENCHANTED study and maximise adherence to ICH GCP, please take 60 seconds to double check the consent form has been completed correctly within the first 2-3 hours that a patient has been admitted. If errors are noted, they can then be rectified immediately, with the relevant study staff and if applicable the family members that were involved.

ENCHANTED Office

Level 10, KGV Building

Missenden Road, Camperdown

NSW 2050, Australia.

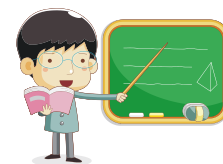
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Helpful Tips for Our Sites

From time to time we like to refresh our International teams working on ENCHANTED of important points to remember for the successful completion of the study. Please take the time to read through the points below:



Serious Adverse Event (SAE) - Form X Completion

- Please enter only **one** event for Q2 on Form X. If there were multiple events diagnosed please report each one in a separate Form X.
- Do not enter 'Death' as the Event Diagnosis (Q2). Please enter the event that resulted in death. Death will be subsequently reported in Q12—Event Code and Q17—Resolution Code.
- Report only **surgical** procedure's in Q16. For example: Craniotomy, carotid endarterectomy. **DO NOT** list medications or other interventions.
- All SAE's are reviewed by an In-house Neurologist at The George Institute. Data queries will be issued on a monthly basis, please respond to these queries within 7 days.

Protocol Violations

Below is a list of the most common protocol violations that have been reported to ICC to date:

1. A copy of the signed Consent Form has not been given or documented as been given to the subject/ person responsible/ legal representative.
2. Day 28 assessment performed outside of protocol allowed window.
3. SAE's not reported within 24 hours of becoming aware of the event.
4. Consent Form missing the signature of the person who obtained consent.
5. Consent form missing Person Responsible/ Legal Representative name.
6. Day 28 Follow up not performed by a blinded assessor .
7. Consent Form missing person obtaining consent date.

- All **MAJOR** Protocol Violations are required to be reported to your local Ethics committee.
- Protocol Violations are to be reported to your RCC / ICC monthly.
- Protocol Violations will also be issued monthly (if applicable) by the RCC/ ICC after review of the database remotely.

Imaging Server

- All Brain Images must be uploaded into the ENCHANTED Imaging Server within **7 days** of Randomisation.
- All images must be de-identified, in an uncompressed DICOM format and converted to a zip file prior to uploading.
- Ensure there is **only 1** patient per zip file, otherwise an error will occur.

Data Queries

- All system generated data queries should be resolved within **7 days** of data entry. Data fields that have triggered a query can be recognised by a **Q** appearing next to the data after a form has been submitted.