

# ENCHANTED News

Enhanced Control of Hypertension and Thrombolysis Stroke Study

Aug 2014 | Issue 8

## Hyperacute BP Control in Clinical Practice

At the recent European Stroke Conference (ESC) in Nice, Professor Philip Bath of the University of Nottingham presented the main results of the ENOS (Efficacy of Nitric Oxide in Stroke) trial which involved over 4,000 stroke patients recruited from 173 hospitals in 23 countries over the last decade. ENOS showed no beneficial effect of modest BP lowering (7/4mmHg over 7 days) from the early use of a nitrate patch on 90-day clinical outcomes. However, the study included only about 7% (~n=280) of patients within 6 hours after stroke onset where even fewer patients had received rtPA, yet there was an apparent significant benefit of the treatment in this subgroup.

These results make the **BP arm of ENCHANTED even more important** as we are looking at a much early intervention (<4.5 hours from stroke onset if randomised in the both rtPA and BP arms of the trial), with a greater BP difference (intervention target 130-140mmHg). Recruitment has been lower than expected in the BP arm BUT could be very important if a lower blood pressure was associated with a lower risk of ICH.

If patients are given routine non-trial rtPA, they can still be randomised in the BP only arm of ENCHANTED provided treatment can be started within 6 hours from stroke onset. We know from the long-term anticoagulation trials that a lower blood pressure is very protective against intracranial haemorrhage, and therefore BP lowering, during acute stroke thrombolysis is a very promising but unproven intervention. We hope that more of you will consider randomisation in the BP arm in the coming months.

## Current Recruitment in ENCHANTED BP arm

As of the 26 August 2014, **568** patients have been enrolled in the BP Arm. We are on track to reach our target of **600** by the end of 2014, which equates to approximately 8 patients / month.



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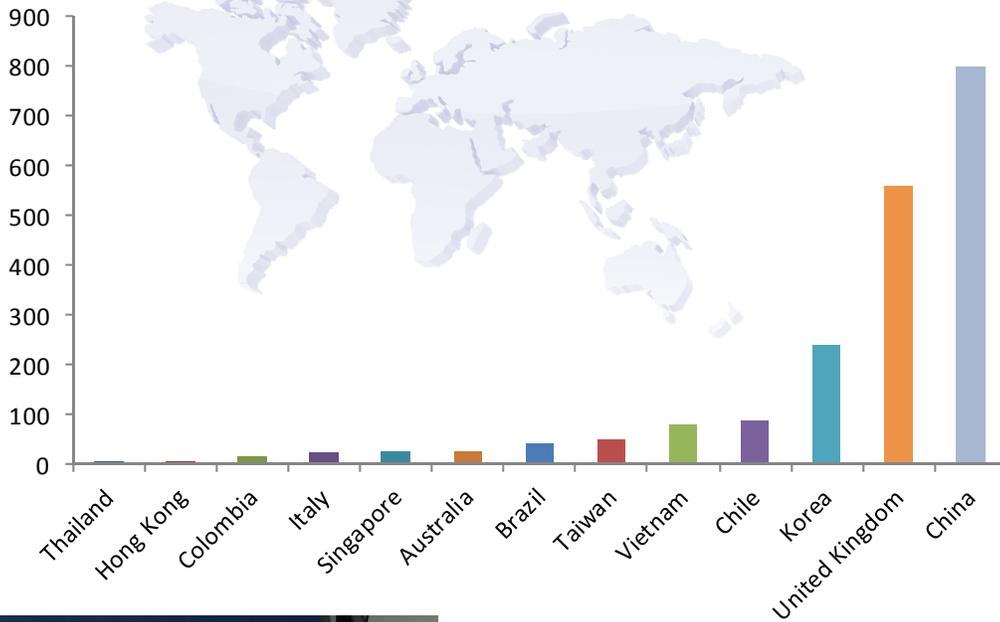
### Special points of interest

- UK enrolls 1500th Patient in to ENCHANTED in April



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for Global Health

## Worldwide Recruitment to 26 Aug 2014



Australia	26
Brazil	43
Chile	84
China	800
Colombia	13
Hong Kong	4
Italy	21
Korea	236
Singapore	25
Taiwan	49
Thailand	2
United Kingdom	557
Vietnam	78



*Congratulations to Kings Mill Hospital in the UK for having the shortest median **Door to Needle** time of **27 minutes!***

The ENCHANTED Team would like to send out a special congratulations to the following countries for obtaining a median door to needle time of 60 minutes or less:

**Korea, Hong Kong, UK, Chile, and Thailand**

The team would like all sites to continue to work hard to overcome barriers at their sites in an aim to have the D2N time to less than 60min for all sites by the end of the ENCHANTED study.

## TOP 10 RECRUITING SITES

Centre	Country	Total
Yutian County Hospital, Hebei Province	<b>China</b>	<b>114</b>
Xuzhou Central Hospital	<b>China</b>	<b>106</b>
Second Affiliated Hospital, Suzhou University	<b>China</b>	<b>95</b>
The Chinese PLA No.263 Hospital	<b>China</b>	<b>91</b>
University Hospital of North Staffordshire	<b>United Kingdom</b>	<b>87</b>
Baotou Central Hospital	<b>China</b>	<b>80</b>
The People's Hospital 115	<b>Vietnam</b>	<b>78</b>
Kings College Hospital NHS Foundation Trust	<b>United Kingdom</b>	<b>74</b>
The First Hospital of Nanjing	<b>China</b>	<b>70</b>
Clinica Alemana	<b>Chile</b>	<b>59</b>

## Life at the George Institute by Shihong Zhang

Visiting fellow from West China Hospital of Sichuan University, China

I am a doctor from China and now working in ENCHANTED ICC team on reviewing SAE reports, CT/MRI image quality and pending queries.

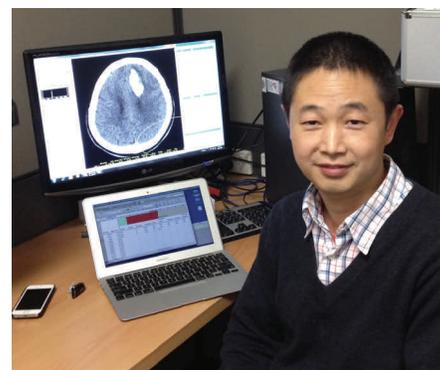
Before I came here I was responsible for data collection in my hospital. It is interesting experience to be a reviewer to assess works all the ENCHANTED participating hospitals are doing. By doing all these, I have got better understanding of the high quality requirements of the ENCHANTED trial.

As we all know every reported SAE is source data verified by

CRAs in ENCHANTED. At the same time every reported SAE is also medically reviewed by neurologists in Sydney and UK to make sure every SAE is medically sound and appropriately coded.

Study outcomes of ENCHANTED are adjudicated by blinded adjudication committee using uploaded brain imaging. Uploading quality ensured CT/MRI imaging in a timely manner is really crucial for the whole process.

All the resolved data queries are double checked again by medical staff in Sydney to



prevent any minor data error, e.g. wrong unit of blood test result.

Every detail of the trial is managed to make sure the integrity of the data.

I'd like to call on Local participating hospitals to keep up high quality of data. I believe ENCHANTED trial will successfully address the very

## Message from the ENCHANTED Brain Imaging Adjudication Team

Prof Richard Lindley, Honorary Professorial Fellow, Neurological & Mental Health Division Injury, Frailty and Disability Theme

Repeat brain imaging is requested for a patient in ENCHANTED to assess whether there has been any bleeding complications following thrombolysis.

Symptomatic intracranial haemorrhage (sICH) is the main

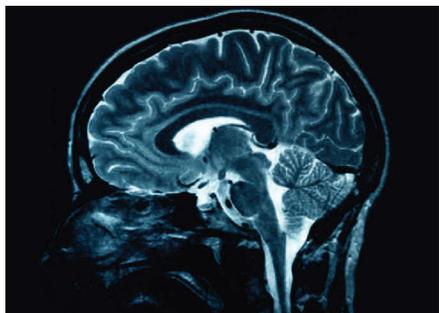
risk of rtPA and is centrally adjudicated in the ENCHANTED study. By measuring the sICH rate in the different treatment groups in ENCHANTED we will be able to demonstrate if a lower dose of rtPA carries a lower risk of sICH, and whether blood pressure lowering can also reduce haemorrhagic complications.

For us to be able to centrally adjudicate these events you must send us all the brain imaging for patient enrolled in ENCHANTED.

CT scanning is very effective at detecting important sICHs and is our preferred imaging modality. If you use MRI, **you MUST include a GRE or T2\* sequence** for us to be able to make an accurate adjudication.

We are still receiving some follow-up MRIs without appropriate sequences for the detection of ICH.

If you have any questions about the adjudication process or the technical requirements for brain images, please contact the ICC at [enchanted@georgeinstitute.org.au](mailto:enchanted@georgeinstitute.org.au)



## ENCHANTED WEIGHS IN AT THE 2014 EUROPEAN STROKE CONFERENCE (ESC)

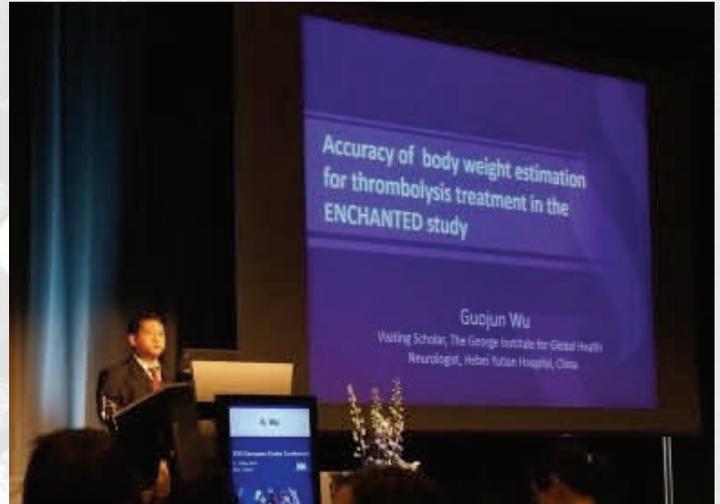
The ENCHANTED Study was represented by 4 Posters and an Oral presentation at this year's ESC.

### *Oral Presentation:*

#### **Accuracy of body weight estimation for thrombolysis treatment in the ENCHANTED study.**

Presented by visiting scholar, Dr Guojun Wu, a Neurologist from Yutian County Hospital, Hebei Province, China

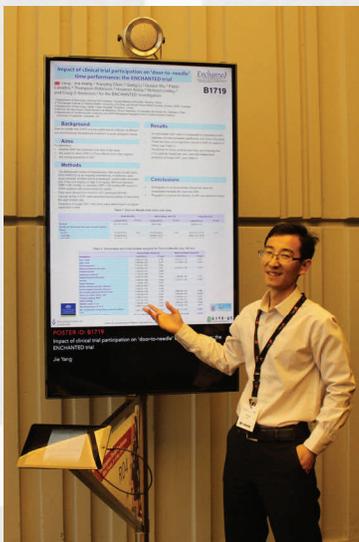
The abstract examined the overall accuracy of body weight estimation in the ENCHANTED study, and whether differences are evident across participating countries. Dr Wu reported that in this large scale, multi-national, multi-centre, clinical trial, there are reasonably accurate estimates of BW across major regions of recruitment and the mean and absolute differences provided no evidence of a systematic bias in BW estimation



### **ENCHANTED (UK Focus)**

#### *Background, Methods & Recruitment*

Professor Tom Robinson, Department of Cardiovascular Sciences, University of Leicester, UK



### *Poster Presentations:*

#### **Impact of clinical trial participation on 'door-to-needle' time performance: the ENCHANTED trial**

Presented by visiting scholar, Dr Jie Yang, a Neurologist from Yutian County Hospital, Hebei Province, China



### **ENCHANTED Part A and ENCHANTED Part B**

#### *Recruitment Updates*

Presented by Global Project Manager Xiaoying Chen, The George Institute for Global Health, Sydney, Australia

# 23. European Stroke Conference

## **Enchanted**

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**THE GEORGE INSTITUTE**  
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# 6 - 9 May 2014

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