

ENCHANTED News

Enhanced Control of Hypertension and Thrombolysis Stroke Study

January 2017

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*We hope you had an enjoyable holiday season! Wishing you a successful **2017!!***

Keep your Fantastic work on Arm B Recruitment !!!

To remind you, these are our key eligibility criteria:

1. Patients with acute ischaemic stroke for whom rt-PA thrombolysis is indicated and planned, no matter what dose
2. Baseline BP \geq 150mmHg
3. Able to commence allocated treatment within 6 hours of stroke onset

Brain imaging requirements

As a key secondary outcome for patients in ENCHANTED is the degree of symptomatic intracranial haemorrhage, you must order the correct MRI sequences if you opt to perform MRI rather than CT. To reliably detect haemorrhage we need a **Gradient Echo sequence**, often referred to as **GRE** or **T2***. Without a T2* sequence, it can be difficult to adjudicate the presence or absence of haemorrhage.

We also recommend you order a **diffusion weighted imaging sequence** as this allows us to determine whether the bleeding was within the infarct area. It can be surprisingly difficult to identify bleeding on the structural imaging sequences of T1, T2 or FLAIR.



New Year Eve—Sydney Harbour Bridge



Message from Professor Richard Lindley

Honorary Professional Fellow, Neurological & Mental Health Division (Injury, Frailty and Disability)

Thank you to all of you who have randomised patients into the ENCHANTED Study during the **2016**.

Our total recruitment in the blood pressure (BP) arm by **31st December 2016** was **1,498 participants** which is **65%** of our **TARGET** of **2,304**. To achieve this target we need your continued enthusiastic screening and recruiting. For those of you who have not recruited recently, please review your local research plans and consider prioritising ENCHANTED. We really appreciate your efforts. Any questions, please contact the ENCHANTED ICC Team. We are here to support you on running the study.

The ENCHANTED Study asks a really **important question**, and one that clinicians have been asking ever since thrombolysis became a routine treatment, what should we do about BP? The recent observational data from IST-3 (reviewed in previous newsletters) supports BP lowering but we now need data from a randomised controlled trial to confirm this promising observational data (Stroke 2015; 46: 3362-3369). The repeat brain imaging is of crucial importance so please request the GRE/T2* and DWI sequences if using MRI. These sequences will provide extremely valuable detail for our dedicated panel of central brain imaging adjudicators.

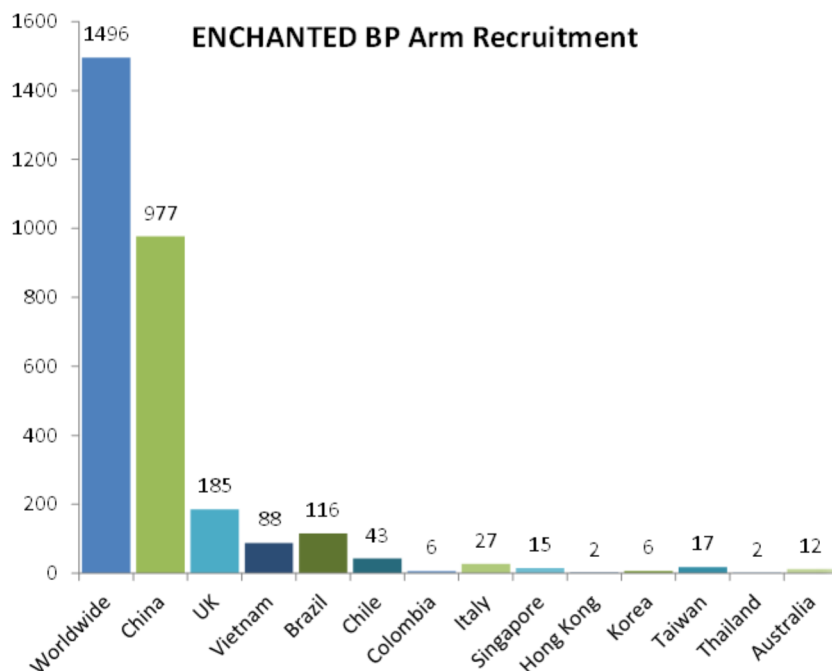
One of our key eligibility criteria is that BP lowering can commence within 6 hours of stroke onset. The 6-hour time window allows you to start rt-PA treatment and then consent potential eligible patients, so this will not increase your door-to-needle times, so crucial for many of you.

Whilst we seek to **increase GLOBAL recruitment**, we also want good data. Thus, we would like to share with you some tips for BP arm recruitment. If you need to pre-treat patients with severe hypertension to achieve rt-PA eligibility (e.g. treating arrival BPs over 185mmHg to get the patient below 185mmHg for safe thrombolysis), consider using a GTN patch or infusion. Once the BP is under 185 mmHg you can then safely treat with rt-PA, and you can then assess for the ENCHANTED Study. If the BP is within our trial eligibility (**150 to 185mmHg**), you can consent and randomize. The glyceryl trinitrate (GTN) patch or infusion is easy to stop, should the patient be within the safe BP zone (150-185 mmHg) and be allocated to control in the trial. If the patient is allocated to BP lowering, you can continue the GTN patch, and consider adding your preferred additional anti-hypertensive medication.

Finally, we would like to share with you some good news. India will begin recruitment soon.

Congratulations to *Professor Jeyaraj Pandian* and his National Team of investigators for joining the ENCHANTED Study Network!! Please welcome them!.

Country Performance on Recruitment as of 31st of December 2016

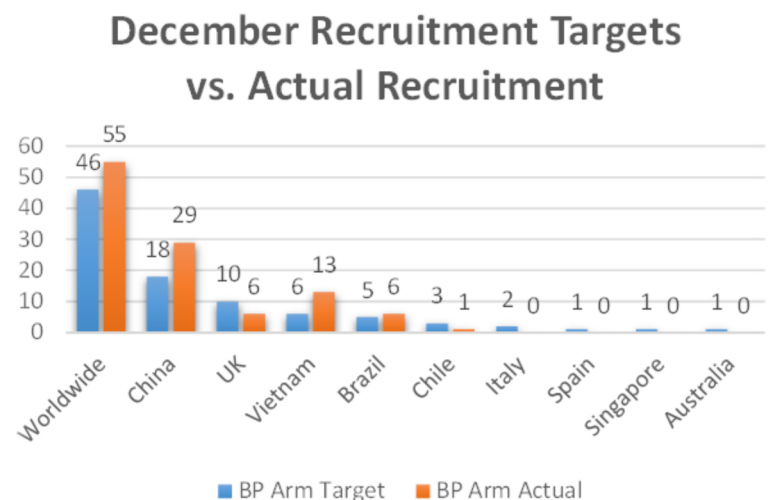


1496 patients recruited from our **TARGET** of **2304**

65% TARGET

We still need 808 patients to go as July 2018!

- ◆ **55** patients recruited in **Dec 2016**
- ◆ More than **100%** of the target was reached.
- ◆ **Congratulations for your constant efforts!**



TOP 5 RECRUITING SITES: DECEMBER 2016

Centre	Country	Total
Xuzhou Central Hospital	China	16
Bach Mai Hospital	Vietnam	6
Gai Dinh People's Hospital	Vietnam	4
Hospital Governador Celso Ramos	Brazil	4
The Affiliated Hospital of Jining Medical University AND The People's Hospital 115	China-Vietnam	3

Brain imaging collection rates as of 8th December 2016

Country	Patients enrolled	Discrepancy between IS and DB*	Patients with all scans uploaded	Rate of scan upload
Worldwide	516	17	342	66.3%
Australia	3	0	3	100.0%
Chile	2	0	2	100.0%
Italy	7	0	7	100.0%
Singapore	7	0	7	100.0%
UK	117	8	91	77.8%
Vietnam	52	0	33	71.7%
China	282	9	166	58.9%
Brazil	38	0	20	52.6%

CRF completion rates as of 12th December 2016

Country	Expected complete patients	Complete eCRF in Study Database	Complete Patient Data Rate	Outstanding Day 90
Worldwide	1322	1184	90%	68
Italy	27	27	100%	0
Singapore	15	15	100%	0
Chile	42	41	98%	0
Brazil	102	95	93%	2
Australia	12	11	92%	0
China	893	809	91%	54
UK	171	139	81%	9
Vietnam	60	47	78%	3

BP difference at 1 h by Country as of 12th December 2016

Country	Current Recruitment in BP arm	SBP at 1hr Control Group	SBP at 1hr Intensive BP Group	BP difference at 1 hr
Worldwide	1455	153	145	8
Italy	27	157	141	16
Chile	42	161	146	15
Brazil	112	154	145	9
China	957	151	143	8
Vietnam	77	149	144	5
Taiwan	17	167	162	5
United Kingdom	180	159	155	4
Singapore	15	154	157	-3
Colombia	6	136	139	-3
Korea	6	138	142	-4
Australia	12	149	159	-10

ICC News!

Congratulations to **Sharon Tucker** (ENCHANTED Clinical Research Associate) on the birth of her beautiful girl in **December 2016!!**.