NEWSLETTER

SPRING 2011

woman
World Maternal Antifibrinolytic Trial

1,400 WOMEN ALREADY ENROLLED!

Randomisation by site

RECRUITMENT STILL OPEN TO NEW SITES

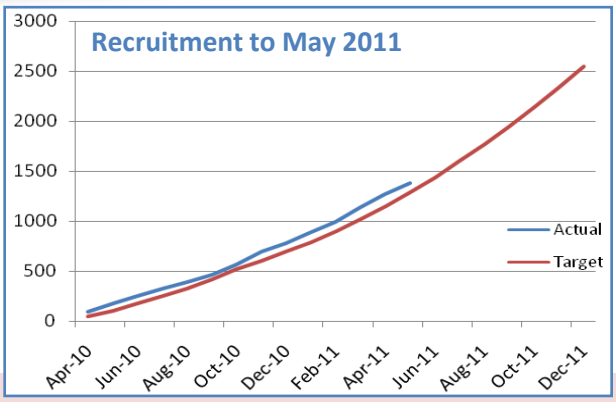
Please let your obstetric colleagues in other hospitals know about the trial and that there is still the opportunity to join this global effort.

Dear Collaborators,

It has been a hugely successful year! Congratulations to the global team of WOMAN trial collaborators on some major achievements:

- *Recruitment remains ahead of our planned target – this is good news for patients – the sooner we answer this important question the better!*
- *Data from the first 1,000 patients have now been reviewed by the Independent Data Monitoring Committee. They congratulated the collaborators on recruitment and the quality of the data. There were no safety concerns. They recommend that we continue as per Protocol.*

Congratulations !!! Your Trial Coordinating Centre



ACHIEVEMENTS

The first participating teams to reach significant milestones are listed here. Thank you all for your enthusiasm and dedication!

100 PATIENTS

BP Koirala Institute of Health Sciences Nepal, PI Mohan Regmi

50 PATIENTS

Federal Medical Centre Katsina, Nigeria
PI Babasola Okusanya

Hôpital Laquintinie de Douala, Cameroon
PI Tschele Mesack Tchana

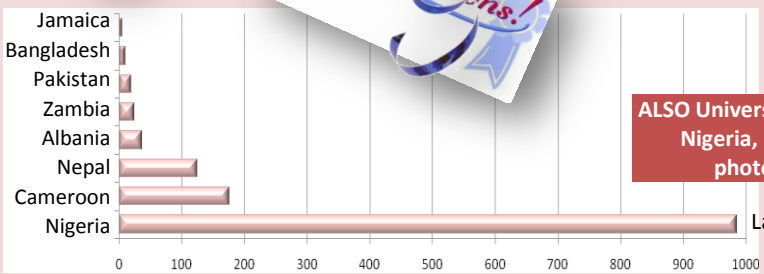
Irrua Specialist Teaching Hospital, Nigeria
PI Felix Okogbo

University Of Ilorin Teaching Hospital, Nigeria,
PI Abiodun Peter Aboyeji

University Of Calabar Teaching Hospital, Nigeria
PI Saturday Job Etuk

ALSO University of Abuja Teaching Hospital, Nigeria, PI Olatunde Onafowokan – photo in the next newsletter

Lagos University Teaching Hospital, Nigeria, PI Omolulu Adegbola

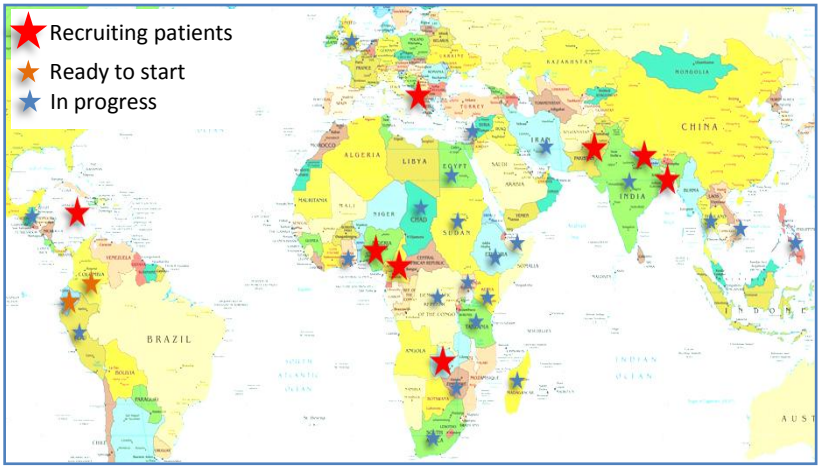


POINT TO DISCUSS WITH YOUR TEAMS: CONSENT

A National Ethics Committee visited one of the recruiting sites and identified the following issue:

About 5am one morning a woman was enrolled into the trial. She was bleeding and unwell and it was difficult for the doctor on call to fully counsel her about the trial.

Although she signed the consent form, she later explained to the Ethics Committee that she had not realised that the treatment she had been given was part of a trial.



THE ETHICS COMMITTEE WAS RIGHT TO RAISE THIS

If a woman is asked to sign a consent form, then it is assumed…

- **That the woman had the capacity to do so,** which means that she had the ability to make decisions based on the information provided.
- **That the doctor had disclosed information needed for her to understand the trial and its procedures.** This information includes the nature and purpose of the treatment as well as its risks, potential benefits, and any available alternatives.
- **That the woman was able to understand** the information given and appreciate its relevance to her individual situation.
- **That the woman then gave her authorisation** allowing the trial team to carry out the trial procedures.
- **That her authorisation was voluntary** – this means free from any 'coercion', unfair persuasions or inducements.

Getting properly informed consent takes time. It takes time for the woman or her representative to read and absorb the information, ask questions, reflect on their decision, and complete the consent form (if able to read and write). If a doctor has to complete sections of the form in order to speed up the process, then there is not enough time for a valid, written, informed consent to be obtained.

CONSENT MEANS MORE THAN HAVING A SIGNED FORM

WHAT SHOULD THE DOCTOR DO IN THE EMERGENCY SITUATION?

The protocol makes it clear that women with PPH are in a critical condition and likely to lose their capacity to make a judgement. Both clinical and trial interventions must be given rapidly and as soon as possible after the diagnosis is made, as the risk of death is highest early after delivery.

The doctor in this example should recognise that…

- the woman does not have full capacity to make a decision;
- there is insufficient time to explain the trial.

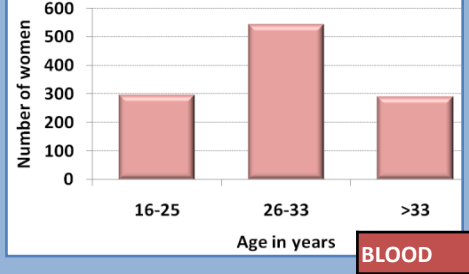
Therefore she could not reasonably be expected to give her written consent.

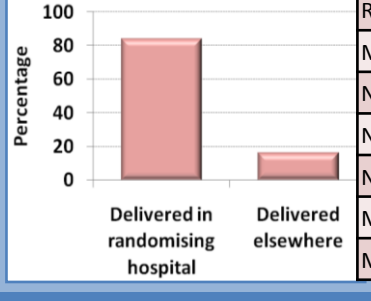
If proper informed consent cannot be obtained, the Protocol allows for the investigator and ONE independent person (a doctor or midwife not taking part in the trial) to enrol the woman by writing in the woman's medical records that…

- the woman is facing a life threatening postpartum haemorrhage;
- the woman is unable to give her consent as a result of her medical condition;
- it is not feasible to contact her representative to obtain consent **within the time window period**; and
- neither the woman nor her representative nor any member of the family has informed the investigator of any objections to the woman being used as a participant in this trial.

If enrolled under such emergency consent procedure, the woman or her representative should be informed about the trial as soon as it is possible, and asked to consent for continuation of any trial procedure.

DATA ACQUIRED FROM THE FIRST 1,000 PATIENTS





UTEROTONICS	N (%)
Oxytocin	1014 (97%)
Ergometrine	611 (58%)
Misoprostol	509 (48%)
Prostaglandins	44 (3.2%)

BLOOD	N (%)
Received transfusion	572 (534.5%)
Median (range) units–**whole blood/packed cells**	2 (1–12)
Number (%) with 1 unit	155 (27%)
Number with 2–8 units	403 (70%)
Number with >8 units	13 (2.3%)
Median (range) units–**fresh frozen plasma**	2 (1–16)
Median (range) units–**other blood products**	3 (2–8)

PROCEDURE	N (%)
ANY intervention	258(24.6%)
Hysterectomy	55 (5.2%)
Brace sutures of the uterus	27 (2.6%)
Arterial ligation/embolisation	24 (2.3%)
Laparotomy for other bleeding reasons	21 (2.0%)
Manual removal of placenta	137 (13.0%)
Intrauterine tamponade	45 (4.3%)

EVENT	TOTAL	%
Women who died	49	4.7%
Women with hysterectomy	55	5.2%
Women who died after hysterectomy	7	0.5%
Overall event rate		**9.4%**

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