

# WOMAN TRIAL IN NIGERIA



## COUNT DOWN TO FIRST PATIENT!

In December 2008 a group of Nigerian obstetricians came together with the Trials Coordinating Centre team from LSHTM to discuss initial ideas for the WOMAN Trial. The enthusiasm for the trial by the Nigerian team and the relevance of this trial to the women of Nigeria were major factors in moving the idea forward.

Dr Olayemi Oladapo from University College Hospital Ibadan, as a member of the Trial Steering Committee, has critiqued the protocol to ensure that it is relevant to the Nigerian women. In this newsletter he explains why this trial is important to Nigeria. We have in place a motivated, hardworking and committed Nigerian National Coordinator, Dr Bukola Fawole, who has worked tirelessly to get the NHREC approval and will shortly have the NAFDAC approval for the first phase hospitals. Also in this newsletter, Dr Fawole explains why this trial must succeed in Nigeria.

All the investigators named below have shown their commitment through their work in completing their Good Clinical Practice training, the documentation necessary for the NHREC and NAFDAC submissions, and making submissions to their Local Ethics Committee. The trial will be ready to start recruitment in about two weeks.

The Nigerian team should be proud of their achievements so far – you already have the largest team (24 hospitals) in any one country, committed to making the trial a success and on target to be the first to start the trial.

In less than one year from the idea, the trial will be ready to start in Nigeria. A meeting is planned for active investigators in the first week of March 2010 in Ibadan. This meeting will aim to share ideas and address problems to ensure the trial will be successful. We expect all investigators to have started recruitment before the meeting. Further information will follow soon.

*The TCC team*

RECRUITING NEW SITES IN NIGERIA! PLEASE TELL YOUR COLLEAGUES IN OTHER HOSPITALS ABOUT THE WOMAN TRIAL.

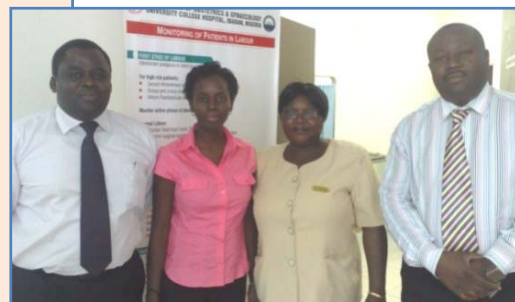
### SITES INCLUDED IN THE FIRST NHREC APPROVAL

#### and their Principal Investigators

- National Hospital Abuja, Dr Olubunmi Ladipo
- Adeoyo Maternity Hospital, Dr Ayinde Akintunde Kehinde
- Federal Medical Centre Gusau, Dr Kamil Shoretire
- Federal Medical Centre Katsina, Dr Babasola Okusanya
- Federal Medical Centre Makurdi, Dr Andrea Jogo
- Lagos University Teaching Hospital, Dr Omololu Adegbola
- Ladoke Akintola University of Technology Teaching Hospital, Dr Adetunji Oladeni Adeniji
- Obafemi Awolowo University Teaching Hospital, Dr A Babalola Adeyemi
- Olabisi Onabanjo University Teaching Hospital, Dr Olufemi Oladapo
- University College Hospital Ibadan, Dr Oladapo Olayemi
- University of Abuja Teaching Hospital, Dr Olatunde Onafowokan
- University of Ilorin Teaching Hospital, Dr Abiodun Peter Aboyeji



FMC AZARE team: sitting PI Dr Umar Nasiru Ibrahim, standing from left Dr Yusuf Baffah, Dr Ardo Abdullahi, Sister Suwaiba Muhammed



IBADAN UCH team: PI Dr Oladapo Olayemi, Dr Mrs Folashade Bello, the matron Mrs Fadiyimu, Dr Christopher Aimakhu



SDA ILE-IFE team: Dr Herb Giebel, Dr Mrs Sonibare Omowonuola, RN/RM Nike Adeniregun, RN/CHO Samson Popoola. The PI Dr Jason Lohr is not in the photo.



FMC BIRNIN-KEBBI team: Dr Aisha Adamu, PI Dr Jaiyeola Oyetunji, Mrs Bunmi Adams



JOS UTH team: Dr D D Nyango, Mrs Jummai Bawa (Matron I/C Labour Room), PI Dr J T Mutihir, Dr J Musa, Dr J Karshima



## WHY THE WOMAN TRIAL IS IMPORTANT TO NIGERIA

*Dr Oladapo Olayemi, Principal Investigator, University College Hospital Ibadan; Member of the Trial Steering Committee*

Globally, about 500,000 women die annually from childbirth and its complications, and of these women 10% come from Nigeria, with less than 2% of the world population.

Among those that die in Nigeria, obstetric haemorrhage, including post-partum haemorrhage, is the leading cause. Blood for transfusion required to save life is in short supply. This trial is about a regimen that is likely to reduce the need for blood transfusion and reduce maternal mortality.

Moreover, there are some racial differences in diseases, response to medications, and even disease severity and progression. Nigeria is predominantly a black nation and the most populous black nation in the world. It is therefore necessary, if this trial is to be generalized to the black races, that Nigeria contributes.

*The Nigerians would be among the greatest beneficiaries from the WOMAN trial and it is therefore important to Nigeria that this trial is successful.*

These sites and Principal Investigators are in various stages of preparing for the next NHREC submission which is impending:

- ❖ Federal Medical Centre Abeokuta, Dr Moses Oluwafemi Alao
- ❖ Federal Medical Centre Birnin-Kebbi, Dr Jaiyeola Oyetunji
- ❖ Federal Medical Centre Owerri, Dr Emily Nzeribe
- ❖ Federal Medical Centre Owo, Dr Olufemi Odunayo Akinsanya
- ❖ Irrua Specialist Teaching Hospital, Dr Felix Okogbo
- ❖ Jos University Teaching Hospital, Dr Josiah Mutihir
- ❖ Lagos State University Teaching Hospital, Dr Oluwarotimi Ireti Akinola
- ❖ Nnamdi Azikiwe University Teaching Hospital, Dr Joseph Ikechebelu
- ❖ Port Harcourt University Teaching Hospital, Dr Chris Akani
- ❖ Seventh Day Adventist Hospital Ile-Ife, Dr Jason Lohr
- ❖ Federal Medical Centre Azare, Dr Umar Nasiru Ibrahim
- ❖ University of Uyo Teaching hospital, Dr Aniefiok Umoiyoho



The last two have already managed to obtain local ethics approval from their hospital – great progress!



If you are attending the annual conference of the Society of Gynaecology and Obstetrics of Nigeria (SOGON) in Kano on 17-20 November, do try to meet up with Dr Fawole to discuss any queries you might have about the WOMAN trial.



## WOMAN Trial Must Succeed in Nigeria

*Dr Bukola Fawole, National Co-ordinator*

The World Maternal Antifibrinolytic (WOMAN) trial aims to assess effectiveness of tranexamic acid in the treatment of women with postpartum haemorrhage (PPH). PPH is the most common cause of maternal death worldwide. Reports from Nigeria indicate that PPH is the leading cause of maternal mortality accounting for between a quarter and one third of all deaths. (Ujah et al, 2005; Abe and Omo-Aghoja, 2008)

Given recent evidence that maternal mortality is rising in Nigeria (UNICEF 2008), it may be assumed that PPH is also on the increase. Consequently, PPH remains a priority health problem in Nigeria and all PPH related research is in the country's best interest. A recent review of the evidence base of treatment modalities for PPH by the World Health Organization revealed that "there have been no randomized controlled trials on the use of tranexamic acid for the treatment of PPH following vaginal delivery that address the priority outcomes" (WHO 2008). It is reassuring that the WOMAN trial addresses this gap in research.

Therefore, it is important that the trial should succeed in Nigeria. Signs that the trial will succeed are already evident. We have witnessed quiet efficiency in the operations of the National Health Research Ethics Committee (NHREC) and Registration and Regulatory Affairs Directorate of NAFDAC. NHREC has already given ethical approval for the first set of 12 collaborating sites while we await regulatory approval from NAFDAC.

*Enthusiasm shown by Principal Investigators and their departments and institutions is also encouraging. More health facilities are expected to join the trial. We look forward to commencement of patient recruitment and a successful trial.*



FEDERAL MEDICAL CENTRE ABEOKUTA team, PI Dr Moses Oluwafemi Alao in the middle

### References

- World Health Organization. WHO guidelines for the management of postpartum haemorrhage and retained placenta. Geneva: World Health Organization, 2008
- Ujah IAO, Aisien OA, Mutihir JT, Vanderjagt DJ, Glew RH, Uguru VE. Factors contributing to maternal mortality in North-Central Nigeria: A seventeen year review. Afr J Reprod Health 2005; 9: 27 – 40.
- Abe E, Omo-Aghoja LO. Maternal mortality at the Central Hospital, Benin City Nigeria: A ten year review. Afr J Reprod 2008; 12: 17 – 26.
- UNICEF. The state of the world's children 2009. Maternal and newborn health. New York: United Nations Children's Fund, 2008.

Check out the trial website for information and training materials. For username and password for the INTRANET please email the TCC.



### Trials Coordinating Centre

LSHTM, Room 180, Keppel Street, London WC1E 7HT, UK  
tel +44(0)20 7299 4684, fax +44(0)20 7299 4663, email [thewomantrial@lshtm.ac.uk](mailto:thewomantrial@lshtm.ac.uk)  
[WWW.WOMANTRIAL.LSHTM.AC.UK](http://WWW.WOMANTRIAL.LSHTM.AC.UK)

