

Trial Coordinating Centre, Clinical Trials Unit, 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 www.womantrial.Lshtm.ac.uk

WOMAN TRIAL IN SUDAN



Many people believe that they do not have what it takes to make a difference in the world. However, every one of us is able to contribute and make a difference. To do good research that can improve outcomes for the people we look after, requires the contribution of many, many people.

The WOMAN trial which aims to improve outcomes for women who have their lives destroyed by postpartum haemorrhage (PPH) is one endeavour where collaborating together globally will allow us to make a difference. In Sudan, obstetricians, midwives, nurses and doctors in training have all started contributing to this global effort that will answer the question as to whether the use of tranexamic acid can reduce mortality and hysterectomy for women who develop PPH.

We were honoured to be invited to the 25th Congress of the Obstetrical and Gynaecological Society of the Sudan in February, to present the WOMAN trial and also to visit some of the collaborating hospitals. A special thank you to **Professor** Abdelatif Ashmaig, President of OGSS, and the organising committee for their support. The dedication of the Sudanese WOMAN trial team to this successful trial was obvious. Professor Mohamed El-Sheikh is an inspirational National Coordinator and has the support of a dedicated team led by Taha Umbeli at Omdurman Maternity Hospital, Wisal Nabag at Khartoum North Hospital, Abdalla Ali Mohammed at Kassala New Hospital, Khidir Awadalla at El-Obeid Hospital, Mohamed Awad at Soba University Hospital, and Duria Rayis at Khartoum Teaching Hospital. Many more teams have pledged to join the WOMAN trial collaboration in Sudan, including Wad Medani Teaching Hospital (Somia Khalfalla Abdelrahiem), Port Sudan Maternity Hospital (Ammar Mohamed Juma), Elribat University Hospital (Mohamed Ahmed A/Gadir Elimam Ounsa), Gadarif Hospital (Huaida Maidi Mohammad), and Elmek Nimir University Hospital (Saeed Abdelrahman Abdelgabar).

However, our most important memory that will stay with us forever is the kindness, friendliness and humanity of all we met. Onwards to a very successful WOMAN trial in Sudan. Haleema and Danielle

Khartoum North Teaching Hospital, PI Wisal Nabag







The WOMAN trial is important for my hospital because it is investigating the leading cause of maternal mortality, so we participate to reduce maternal mortality in Sudan. The trial is important for me because I am interested in conducting research and have published papers locally and internationally. This experience has helped me to create a co-operative team at KNTH. Is it is important to collaborate because by collaborating we can have contact with international researchers and gain more experience.















Wisal Nabag received a little gift to reward the team for randomising 50 patients into the trial. Certificates of Contribution were awarded to Mohamed Babiker Nor, Sister Mai Omer Yousif and also the Head of Department Obstetrics.

Elmek Nimir University Hospital



I think the WOMAN trial is very important in the reduction of maternal mortality and morbidity. We have a high incidence of PPH and I am one of a large group of doctors working in reducing maternal morbidity and mortality. By joining this study I think we will be in the right track. Dr Saeed

Elribat University Hospital

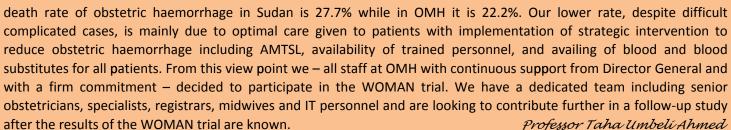
A woman's death due to any cause is a sad story for the family – in fact it is a tragedy. The causes of maternal death are numerous; among them the obstetric haemorrhage remains a leading cause in many countries in the world, especially in the developing countries. Currently there are many preventive and treatment modalities. As an obstetrician, it is my dream to see that women's death due to obstetric haemorrhage is completely eradicated. The WOMAN trial using tranexamic acid gives great hope to minimise these deaths. I am strongly willing to join the trial because I see a spot of light that the trial will achieve this goal. I am optimistic.

Professor Mohamed Ahmed A/Gadir Elimam

Omdurman Maternity Hospital

OMH is the main specialized maternity hospital in Sudan, established in 1957, with over 35,000 deliveries last year. We are an important training center with an average of 180 registrars, 250 house officers and 100 midwives and health visitors trained each year. There are good variable study materials and a good number are training in research, patient care and environment.

According to the national maternal death review 2012, MMR for Sudan is 189/100,000 LB, while in OMH it is 75/100,000 LB. The



Everu







Murwan Ibrahim Omer (Director General), Taha Umbeli (PI) and Weil Umbeli received Certificates of Contribution

El-Obeid Teaching Hospital

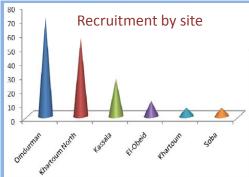
In our hospital all team members believe in the WOMAN trial as a scientific means for improving the outcome of the management of PPH in low resource settings, and by so doing will considerably reduce Maternal Mortality Rates.





Mohamed Awad Ahmed Soba University Hospital

Khidir Elamin Awadalla, Associate Professor







Sudan, one of the low income countries of the Sub-Saharan Africa, has a high maternal mortality ratio. In a recent survey for maternal mortality, it was shown that postpartum haemorrhage (PPH) is the leading cause of maternal death, albeit hypertensive diseases, eclampsia and infection are still the next most common causes.

With the poor roads, inadequate means of transport, limited blood transfusion facilities, lack of coverage of antenatal care and low prevalence of hospital deliveries, PPH remains a great burden for caregivers and a nightmare for the women and their families. Every measure that can reduce death and complications from PPH is greatly needed to be developed.



Ever since the discovery of ergometrine and its use in the management of PPH due to uterine atony, great strides have been taken into this field. Oxytocin drugs, prostaglandins as well as synthetic analogues of both are used with a degree of



effectiveness in the management of PPH. New surgical techniques have also been developed, but with the known complications of surgery, especially in limited resource settings, research in new non-surgical interventions is required.

Tranexamic acid has been shown to reduce death and the need for blood transfusion in bleeding trauma patients. Aware of the WOMAN trial, we in Sudan decided to participate as the results may positively affect the management of PPH in our setup. The WOMAN trial was introduced in Sudan early in 2011 and the first case was randomised on 13 September 2011. Six hospitals are now actively recruiting, while another five are in the process of ethical clearance.

The 25th Congress of the Obstetrical and Gynaecological Society of the Sudan (OGSS) was held in Khartoum in February 2013 and attended by Haleema Shakur and Danielle Beaumont from the LSHTM Clinical Trials Unit. Three sessions were allocated to the WOMAN trial, Haleema Shakur, Taha Umbeli, the PI at Omdurman Maternity Hospital, and Mohamed ElSheikh, the Sudan National Coordinator, presented three papers in the main congress sessions. Photos of some of the participants can be seen above and elsewhere in this newsletter.

A parallel session was dedicated to the WOMAN trial and attended by eighty Sudanese obstetricians and gynaecologists for an interactive discussion and an exchange of ideas. The principal investigators of the participating hospitals gave presentations about their experiences and the difficulties they have encountered. Many obstetricians and gynaecologists showed great enthusiasm and interest in joining the study and six hospitals have already made contact.

Professor Mohamed Ahmed ElSheikh, Sudan National Coordinator







Ammar Ahmed, Dean of Faculty of Medicine, University of Khartoum, received a Certificate

a study file

Kassala New Hospital



Three months from starting recruitment, we are now randomising patients at the rate of seven cases per month. Interns and a midwife have been added to the team and have been delegated different tasks. We feel confident and randomisation is going smoothly. It is great to be in this trial and see that our simple contribution is taking the trial towards the target.

Professor Abdalla Alí Mohammed