STUDY PROTOCOL WITH STATISTICAL ANALYSIS PLAN

Official Title:

Effect of Umbilical Vein Injection of Oxytocin in Addition to Active Management of Third Stage of Labour: A Study Among Parturients at Ahmadu Bello University Teaching Hospital Zaria

Field	Details
Protocol Version	Version 1.0
Date of Protocol	December 2017
Ethics Approval Number	ABUTHZ/HREC/C08/2017
NHREC Number	NHREC No. 10/12/2015
D-U-N-S Number	D-U-N-S No. 954524802
NCT Number	[To be assigned upon registration]
Sponsor	Ahmadu Bello University Teaching Hospital, Zaria
Principal Investigator	Dr. Dangana Z.A.
Department	Dept. of Obstetrics and Gynaecology, ABUTH, Zaria
Approval Period	14 February 2018 to 14 February 2019
Study Period	February 2018 to August 2019
Document Date	14 February 2018

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1. STUDY SYNOPSIS

Field	Description
Full Title	Effect of Umbilical Vein Injection of Oxytocin in Addition to Active Management of Third Stage of Labour: A Study Among Parturients at Ahmadu Bello University Teaching Hospital Zaria
Study Design	Randomized, double-blind (triple masking), placebo-controlled, parallel-group clinical trial
Phase	Not Applicable (licensed drug, alternative route)
Primary Purpose	Treatment
Condition	Postpartum haemorrhage; Third stage of labour; Retained placenta
Intervention	Intra-umbilical vein injection of 20 IU oxytocin diluted in 18 ml normal saline (total 20 ml) vs. 20 ml plain normal saline (placebo)
Sample Size	416 (207 oxytocin group; 209 placebo group)
Primary Outcomes	1. Postpartum blood loss (drape weight method, within 1 hour) 2. Duration of third stage of labour (stopwatch) 3. Change in maternal haemoglobin (labour vs. 24 hours postpartum)
Study Site	Labour and Postnatal Wards, Ahmadu Bello University Teaching Hospital, Shika-Zaria, Kaduna State, Nigeria
Study Duration	February 2018 to August 2019
Sponsor	Ahmadu Bello University Teaching Hospital, Zaria
Principal Investigator	Dr. Dangana Z.A., Department of Obstetrics and Gynaecology
Ethics Approval	ABUTHZ/HREC/C08/2017; Approved 20 December 2017

2. INTRODUCTION AND BACKGROUND

Postpartum haemorrhage (PPH) remains one of the leading causes of maternal morbidity and mortality worldwide, accounting for approximately 25% of all maternal deaths. The majority of these deaths occur during the third stage of labour, the period between delivery of the baby and expulsion of the placenta. In sub-Saharan Africa, the maternal mortality ratio remains disproportionately high, and haemorrhage is the leading direct cause.

Active management of the third stage of labour (AMTSL) with intramuscular oxytocin and controlled cord traction is the current standard of care and has been shown to reduce postpartum blood loss. However, in settings where access to blood transfusion and advanced obstetric care is limited, additional low-cost interventions that can further reduce blood loss are needed.

Oxytocin administered directly through the umbilical vein reaches the placental bed via retrograde flow, potentially enhancing localised uterine contraction at the site of placental attachment. This targeted approach may shorten the duration of the third stage of labour, reduce the volume of postpartum blood loss, and help preserve maternal haemoglobin. The procedure is simple, inexpensive, and can be performed by trained nurses and midwives.

Umbilical vein injection for the management of retained placenta was first described by Mojon and Asdrubali in 1826. Recent studies from Turkey, Iran, and the United States have evaluated intra-umbilical oxytocin as an adjunct to AMTSL with varying results. A meta-analysis concluded that routine use of umbilical vein injection of oxytocin is not recommended until new evidence becomes available. This study was designed to contribute such evidence.

3. STUDY OBJECTIVES AND HYPOTHESES

3.1 General Aim

To determine the effect of umbilical vein injection of oxytocin on the third stage of labour when administered in conjunction with active management of the third stage of labour.

3.2 Specific Objectives

- To determine the effect of intra-umbilical vein injection of oxytocin on postpartum blood loss
- To estimate the effect of intra-umbilical vein injection of oxytocin on the duration of the third stage of labour
- To measure the effect of intra-umbilical vein injection of oxytocin on postpartum haemoglobin change

3.3 Hypotheses

Null hypothesis: Umbilical vein injection of oxytocin has no effect on the outcome of the third stage of labour.

Alternative hypothesis: Umbilical vein injection of oxytocin has a significant effect on the outcome of the third stage of labour.

4. STUDY DESIGN

This was a randomized, double-blind (triple masking: participant, investigator, outcomes assessor), placebo-controlled, parallel-group clinical trial conducted at the labour and postnatal wards of Ahmadu Bello University Teaching Hospital (ABUTH), Shika-Zaria, Kaduna State, Nigeria.

ABUTH Shika-Zaria is a tertiary institution with approximately 3,000 deliveries annually. Zaria is a heterogeneous city in Kaduna State inhabited by approximately 975,228 people, located on the high plains of northern Nigeria at 675 metres above sea level.

Design Element	Description
Study Type	Interventional
Study Model	Parallel Assignment
Number of Arms	2
Allocation	Randomized
Masking	Triple (Participant, Investigator, Outcomes Assessor)
Primary Purpose	Treatment
Phase	Not Applicable
Enrollment	416 (Actual)

5. STUDY POPULATION

The study population comprised consecutive, eligible, and consenting parturients undergoing vaginal delivery at the labour ward of ABUTH Shika-Zaria.

5.1 Inclusion Criteria

- Pregnant women aged 18 to 35 years
- Singleton live pregnancy
- Gestational age between 37 and 42 weeks
- Vaginal delivery
- Parity between 1 and 4
- Haemoglobin concentration of 10 g/dl or higher before delivery
- No identifiable risk factors for postpartum haemorrhage
- Willing and able to provide written informed consent

5.2 Exclusion Criteria

- Blood pressure of 140/90 mmHg or higher
- Placenta praevia
- Placental abruption
- History of vaginal bleeding in the index pregnancy
- Previous caesarean section or any uterine scar
- Coagulation disorders
- Instrumental delivery
- Haemoglobin concentration below 10 g/dl
- Multiple gestation
- Fibroids coexisting with pregnancy
- Genital tract lacerations or bleeding episiotomy

6. INTERVENTIONS

Both groups received routine active management of the third stage of labour (AMTSL), which consisted of intramuscular injection of 10 international units of oxytocin within one minute of delivery and controlled cord traction. The intra-umbilical vein injection was administered approximately one minute following the intramuscular oxytocin injection.

6.1 Arm 1: Oxytocin Group (Active Comparator)

Participants received an intra-umbilical vein injection of 20 international units (IU) of oxytocin (Syntocinon) diluted in 18 ml of normal saline to a total volume of 20 ml. The injection was administered immediately after delivery of the baby and cord clamping using a 20 ml syringe with an 18-gauge needle. The umbilical vein was identified as the largest and most centrally positioned of the three umbilical vessels. The solution was injected slowly over approximately 30 seconds at a point 2 to 3 cm from the introitus. A clamp was then applied below the injection site to prevent spillage, and the cord was milked towards the placenta, followed by controlled cord traction.

6.2 Arm 2: Normal Saline Group (Placebo Comparator)

Participants received an intra-umbilical vein injection of 20 ml of plain normal saline. The injection was identical in volume, route, and method of administration to the oxytocin intervention but

contained no active drug. This served as the placebo comparator. The same injection technique, timing, and subsequent procedures (clamping and cord traction) were followed as in the oxytocin group.

Feature	Oxytocin Group	Normal Saline Group
Arm Type	Active Comparator	Placebo Comparator
Intervention Type	Drug	Other
Intervention Name	Oxytocin	Normal Saline Placebo
Solution Content	20 IU oxytocin in 18 ml NS (total 20 ml)	20 ml plain normal saline
Route	Intra-umbilical vein injection	Intra-umbilical vein injection
Number Analysed	207	209
Background AMTSL	IM oxytocin 10 IU + CCT	IM oxytocin 10 IU + CCT

7. OUTCOME MEASURES

7.1 Primary Outcome Measures

Outcome	Measurement Method	Time Frame
1. Postpartum blood loss	Blood collected using a Nightingale drape placed under the parturient immediately after delivery. The drape was weighed before and after use; the difference in weight (grams) was taken as equivalent to blood loss in millilitres.	Within 1 hour after delivery
2. Duration of third stage of labour	Time measured using a stopwatch started immediately after delivery of the baby and stopped upon complete expulsion of the placenta.	From delivery of baby to delivery of placenta
3. Change in maternal haemoglobin	Haemoglobin concentration measured during labour and at 24 hours postpartum using standard laboratory methods. The difference was calculated and expressed in g/dl.	From labour to 24 hours postpartum

7.2 Additional Outcomes Assessed

- Incidence of postpartum haemorrhage (blood loss of 500 ml or more)
- Percentage of placentae remaining undelivered beyond 15 minutes
- Incidence of retained placenta (placenta not delivered within 30 minutes)
- Need for blood transfusion

8. SAMPLE SIZE DETERMINATION

The sample size was calculated using the formula for clinical trial studies:

$$n = D\,[Z_a + Z_b]^2 \times [(P_1 \times (1 - P_1)) + (P_2 \times (1 - P_2))] / (P_2 - P_1)^2$$

Where:

- n = required minimum sample size per comparison group
- D = design effect (assumed to be 2)
- Z_a = Z score corresponding to 95% level of significance = 1.96
- Z_b = Z score corresponding to 80% statistical power = 0.84
- P_1 = proportion with PPH in control group from a previous study = 4% (0.04)
- P_2 = proportion with PPH in experimental group from same study = 0% (0.00)

The calculated minimum sample size was 188 per group. With a 10% attrition allowance (19 participants), the total required was 207 per group, rounded up to 210 per group (total enrollment target: 420). The software WINPEPI version 2.80 was used to generate random numbers for allocation.

9. RANDOMIZATION AND BLINDING

9.1 Randomization

Randomization was performed using computer-generated random numbers (WINPEPI version 2.80). Numbers 001 to 460 were generated and assigned to either the intervention or control group. Each number was printed on a paper, which was stapled, folded, and placed in an opaque sealed envelope. The envelopes were spread in a tray. Each eligible consenting parturient picked one envelope, which was handed to a trained nurse for allocation.

9.2 Blinding (Masking)

Triple masking was employed (Participant, Investigator, Outcomes Assessor). The trained nurse who received the envelope secretly opened it to determine group allocation. She then secretly prepared the assigned solution: either 20 IU oxytocin in 18 ml normal saline or 20 ml plain normal saline. Both solutions were identical in volume (20 ml) and were labelled only as 'for intra-umbilical vein injection,' ensuring that participants and the administering clinician could not distinguish between them.

The primary investigator responsible for measuring all outcome variables (postpartum blood loss, duration of third stage of labour, and haemoglobin change) was blinded to group assignment throughout data collection. Group allocation was disclosed to the investigator only after all outcome measures had been recorded for each participant.

10. STUDY PROCEDURES

10.1 Recruitment

The primary investigator provided education about the study at the antenatal clinic as a form of group counselling. When eligible parturients presented in labour, a brief history was taken and examinations were conducted by a trained registrar or senior registrar. Written informed consent was obtained from all eligible participants.

10.2 Delivery and Intervention

- After delivery of the baby, the umbilical cord was clamped in two places and cut between the clamps to separate the baby.
- Intramuscular oxytocin (10 IU) was administered within one minute of delivery as part of routine AMTSL.
- The pre-prepared intra-umbilical vein injection was administered by a trained registrar or senior registrar using a 20 ml syringe with an 18-gauge needle.
- The umbilical vein was identified as the largest and most centrally positioned of the three umbilical vessels.
- The solution was injected slowly over approximately 30 seconds at a point 2 to 3 cm from the introitus.
- A clamp was applied just below the injection site to prevent spillage of the injected solution.
- The cord was milked towards the placenta, followed by controlled cord traction.
- The placenta was considered retained if it could not be delivered within 30 minutes of delivery.

10.3 Blood Loss Measurement

Immediately after delivery, any liquor on the mackintosh was cleaned. A pre-weighed Nightingale drape was placed under the parturient to collect postpartum blood for one hour. The drape was weighed after collection, and the difference in weight (grams) was taken as equivalent to blood loss in millilitres.

10.4 Duration of Third Stage

A stopwatch was started immediately upon delivery of the baby and stopped upon complete delivery of the placenta. The elapsed time was recorded as the duration of the third stage of labour in minutes.

10.5 Haemoglobin Estimation

Haemoglobin concentration was measured during labour and again at 24 hours postpartum using standard laboratory methods. The difference between the two measurements was calculated and recorded as the postpartum haemoglobin change (g/dl).

11. DATA COLLECTION

The following baseline characteristics were collected for all participants:

- Maternal age (years)
- Gestational age at labour (weeks)
- Parity
- Use of oxytocin during labour (augmentation)

- Baby birth weight (kg)
- Haemoglobin concentration in labour (g/dl)
- Haemoglobin concentration 24 hours postpartum (g/dl)

Data were recorded on a structured proforma and subsequently entered into a computerised database for analysis.

12. STATISTICAL ANALYSIS PLAN

All statistical analyses were performed using the Statistical Package for Social Sciences version 25 (SPSS 25, IBM Corporation, Armonk, NY, USA).

12.1 Descriptive Statistics

Continuous variables were summarised as mean and standard deviation (SD). Categorical variables were expressed as frequencies and percentages. Baseline characteristics of the two groups were compared to confirm the adequacy of randomization.

12.2 Comparison of Groups

Comparison of the two groups regarding the duration of the third stage of labour, postpartum blood loss, haemoglobin change, and other continuous variables was performed using the independent samples Student's t-test after assessment of equality of variances and homogeneity using Levene's test.

Categorical variables (e.g., incidence of PPH, retained placenta) were compared between the two groups using the chi-squared test.

12.3 Level of Significance

A p-value of less than 0.05 was considered statistically significant for all analyses. Results are presented with 95% confidence intervals where appropriate.

12.4 Analysis Population

Analysis was performed on a per-protocol basis. Participants who were randomized but subsequently excluded due to caesarean section (n=18), instrumental delivery (n=4), bleeding genital lacerations (n=8), or absence of trained personnel to administer the injection (n=14) were excluded from the final analysis. A total of 416 participants (207 oxytocin group, 209 placebo group) were included in the final analysis.

12.5 Handling of Missing Data

Participants with incomplete outcome data were excluded from the analysis of the relevant outcome measure. No imputation of missing data was planned.

Analysis	Variable	Statistical Test
Primary	Postpartum blood loss (ml)	Independent t-test
Primary	Duration of third stage (min)	Independent t-test
Primary	Haemoglobin change (g/dl)	Independent t-test
Secondary	Incidence of PPH	Chi-squared test
Secondary	Placenta undelivered >15 min	Chi-squared test
Baseline	Maternal age, GA, parity, birth weight	Independent t-test / chi-squared
Variance	Equality of variances	Levene's test

13. ETHICAL CONSIDERATIONS

Ethical clearance was obtained from the Health Research Ethics Committee (HREC) of Ahmadu Bello University Teaching Hospital, Zaria.

Item	Details
Ethics Committee	ABUTH Health Research Ethics Committee (HREC)
Approval Number	ABUTHZ/HREC/C08/2017
NHREC Registration	NHREC No. 10/12/2015
D-U-N-S Number	954524802
Date of Approval	20 December 2017
Approval Period	14 February 2018 to 14 February 2019

The study was conducted in compliance with the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrolment. Participants were informed of the nature, purpose, and potential benefits of the study. All participants received free haematinics as a benefit of participation.

Participation was voluntary, and parturients were free to withdraw from the study at any time without any impact on their clinical care. Confidentiality of all participant data was maintained throughout the study.

14. SAFETY MONITORING

The intra-umbilical vein injection of oxytocin is considered a low-risk intervention. Oxytocin is a licensed uterotonic drug already administered intramuscularly as part of routine AMTSL. The umbilical vein injection delivers the drug locally to the placental bed with minimal systemic absorption.

All participants were monitored postpartum according to routine institutional protocols. Any adverse events, including excessive blood loss requiring transfusion, retained placenta requiring manual removal, or other complications, were documented and managed according to standard clinical practice. The primary investigator was responsible for safety oversight throughout the study period.

15. STUDY LIMITATIONS

Parturients with risk factors for postpartum haemorrhage, in whom the effect of umbilical vein injection of oxytocin might have been more clearly demonstrated, were excluded from the study. This was a single-centre study, which may limit the generalizability of the findings to other settings.

16. REFERENCES

1. Güngördük K, Asicioglu O, Besimoglu B, et al. Using intraumbilical vein injection of oxytocin in routine practice with active management of the third stage of labor: a randomized controlled trial. Obstet Gynecol. 2010;116(3):619-624.

2. Weeks AD, Alia G, Vernon G, et al. Umbilical vein oxytocin for the treatment of retained placenta (Release Study): a double-blind, randomised controlled trial. Lancet. 2010;375(9709):141-147.

3. Say L, Chou D, Gemmill A, et al. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health. 2014;2(6):e323-e333.

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8. WHO. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Geneva: World Health Organization; 2012.

INFORMED CONSENT FORM

Official Title:

Effect of Umbilical Vein Injection of Oxytocin in Addition to Active Management of Third Stage of Labour: A Study Among Parturients at Ahmadu Bello University Teaching Hospital Zaria

Field	Details
Ethics Approval Number	ABUTHZ/HREC/C08/2017
NHREC Number	NHREC No. 10/12/2015
NCT Number	[To be assigned upon registration]
Principal Investigator	Dr. Dangana Z.A.
Department	Dept. of Obstetrics and Gynaecology, ABUTH, Zaria
Institution	Ahmadu Bello University Teaching Hospital, Shika-Zaria
Date of Approval	20 December 2017
Approval Period	14 February 2018 to 14 February 2019
Document Date	14 February 2018

This Informed Consent Form has been reviewed and approved by the Health Research Ethics Committee (HREC) of Ahmadu Bello University Teaching Hospital, Zaria.

TITLE OF STUDY

Effect of Umbilical Vein Injection of Oxytocin in Addition to Active Management of Third Stage of Labour: A Study Among Parturients at Ahmadu Bello University Teaching Hospital Zaria.

INTRODUCTION

You are being asked to take part in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask questions if anything is not clear or if you would like more information. Take time to decide whether or not you wish to participate.

PURPOSE OF THE STUDY

Bleeding after delivery of a baby is a serious problem that can affect the health of mothers, especially in our environment. The third stage of labour is the period between the birth of the baby and the delivery of the afterbirth (placenta). During this time, some women may bleed heavily.

Currently, all women who deliver in our hospital receive an injection of a medicine called oxytocin into the thigh muscle immediately after delivery, along with gentle pulling on the cord. This is the standard way of managing the third stage of labour and helps to reduce bleeding.

This study aims to find out whether giving an additional injection of oxytocin through the cord of the afterbirth (umbilical vein) can further help to reduce bleeding, shorten the time it takes for the afterbirth to come out, and preserve the level of blood in your body.

WHAT WILL HAPPEN IF YOU TAKE PART

If you agree to participate, the following will happen:

- You will be placed into one of two groups by chance (like flipping a coin). This is called randomization. Neither you nor the doctor measuring the results will know which group you are in until after the study.
- **Group 1 (Oxytocin Group):** After your baby is born and the cord is cut, you will receive an injection of oxytocin medicine (20 units) mixed with salt water through the cord leading to the afterbirth. This is in addition to the routine injection you will receive in your thigh.
- **Group 2 (Salt Water Group):** After your baby is born and the cord is cut, you will receive an injection of plain salt water (which contains no medicine) through the cord leading to the afterbirth. This is in addition to the routine injection you will receive in your thigh.
- A special cloth (drape) will be placed under your buttocks after delivery to collect and measure any blood lost.
- A blood test will be done during your labour and again 24 hours after delivery to check your blood level (haemoglobin).
- The time it takes for the afterbirth to deliver will be measured.
- All other aspects of your care during and after delivery will follow standard hospital practice.

POSSIBLE RISKS AND DISCOMFORTS

The injection through the cord of the afterbirth is given after the baby has already been separated, so there is no risk to your baby. Oxytocin is a medicine that is already routinely used in the management of labour and delivery. The procedure of injecting through the umbilical vein is simple and is not expected to cause you any additional pain or discomfort beyond what is experienced during normal delivery.

The blood tests require a small needle prick, which may cause brief discomfort.

POSSIBLE BENEFITS

If the additional injection of oxytocin through the umbilical vein is effective, it may help to reduce the amount of blood you lose after delivery, shorten the time it takes for the afterbirth to come out, and help maintain your blood level. This may reduce the likelihood of needing a blood transfusion. Even if you do not benefit directly, the information gathered from this study may help other women in the future.

All participants will receive free blood-building tablets (haematinics) as a benefit of participation.

ALTERNATIVES TO PARTICIPATION

If you choose not to participate in this study, you will receive the standard management of the third stage of labour as practiced in this hospital, which includes the routine intramuscular injection of oxytocin and controlled cord traction. Your decision not to participate will not affect your care in any way.

CONFIDENTIALITY

All information collected about you during the course of this study will be kept strictly confidential. You will be identified only by a study number, and your personal details will not be disclosed in any publication or report arising from this study. Only the research team will have access to your records. Data will be stored securely and handled in accordance with the requirements of the Health Research Ethics Committee of ABUTH.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is entirely voluntary. You are free to decline to participate or to withdraw from the study at any time, without giving any reason. Your decision to participate or not will not affect the quality of care you receive at this hospital. If you withdraw, any data collected up to the point of withdrawal may still be used in the analysis unless you request otherwise.

COMPENSATION

There is no financial compensation for participating in this study. However, all participants will receive free haematinics (blood-building tablets).

CONTACT INFORMATION

If you have any questions about this study, your rights as a participant, or if you experience any problems related to the study, please contact:

Principal Investigator: Dr. Dangana Z.A.
Department: Obstetrics and Gynaecology, ABUTH, Zaria
Email: drdangiza@gmail.com

If you have concerns about the conduct of this study or your rights as a research participant, you may contact:

Health Research Ethics Committee (HREC)
Ahmadu Bello University Teaching Hospital, Shika-Zaria
Email: aaborethrec@yahoo.com

AHMADU BELLO UNIVERSITY TEACHING HOSPITAL, ZARIA
CONSENT DECLARATION

Ethics Approval Number: ABUTHZ/HREC/C08/2017

I have read and understood the information provided above about the study titled:

"Effect of Umbilical Vein Injection of Oxytocin in Addition to Active Management of Third Stage of Labour: A Study Among Parturients at Ahmadu Bello University Teaching Hospital Zaria."

- I have been given the opportunity to ask questions and my questions have been answered to my satisfaction.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.
- I understand that relevant sections of my medical records and data collected during this study may be looked at by the research team.
- I understand that my identity will be kept confidential and that I will not be identified in any publication arising from this study.
- I understand that I will receive free haematinics as a benefit of my participation.
- I agree to participate in this study.

_____

Name of Participant

_____ _____

Signature / Thumbprint of Participant Date

_____

Name of Witness (if participant cannot read or write)

_____ _____

Signature of Witness Date

_____

Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date

One copy of this form will be given to the participant and one copy will be retained by the research team.

HEALTH RESEARCH ETHICS COMMITTEE

AHMADU BELLO UNIVERSITY TEACHING HOSPITAL SHIKA,
ZARIA, NIGERIA.

E- mail: abuthshika@yahoo.com website: www.abuth.org

Chief Medical Director: Prof. Lawal Khalil, MBBS, FMCS, FWACS, FRCS(Ed) mni

Chairman, Medical Advisory Committee: Prof Adamu Ahmed: MBBS, (ABU) LLB (ABUL BL, FWACS, FICS, FACS

Director of Administration: Alh. Abdulrahman Salihu, BAPub. Admin) PGDPA, MPA. (ABU) ABAN, ACIPM.

Ag. Chairperson: Prof Aisha I. Mamman MBBS, FMCPath

NHREC No. 10/12/2015

D-U-N-S No. 954524802

ABUTH/HREC/CL/05

DATE: 14th February, 2017

ABUTH HREC FULL ETHICAL CLEARANCE CERTIFICATE

Effect of Umbilical Vein Injection of Oxytocin in Addition to active Management of Third Stage of Labour: A Study among Paturients at Ahmadu Bello University Teaching Hospital Zaria.

ABUTH Ethics Committee assigned number:	-	ABUTHZ/HREC/C08/2017
Name of the principal Investigator:	-	**Dr. Dangana Z. A.**
Address of the Principal Investigator:	-	Dept. of Obstetrics and Gynaecology ABUTH, Zaria
Date of receipt of valid application:	-	15th December, 2017
Date of meeting when final determination On ethical approval was made:	-	20th December, 2017

This is to inform you that the research described in the submitted protocol, the consent forms and other participant information materials have been reviewed and ***given full approval by the Health Research Ethics Committee.***

Please note this approval dates from **14th February, 2018 - 14th February, 2019**

No participant recruitment into this research may be conducted outside these dates.

All informed consent forms in this study must carry the ABUTH HREC number assigned to this research and the duration of ABUTH HREC approval of the study.

This HREC expects that you submit your application as well as an annual report for ethical clearance renewal 3 months prior to expiration of study dates. This is to enable you obtain renewal of your approval and avoid interruption of your research.

If there is delay in starting the research, please inform the ABUTH HREC so that starting dates can be adjusted accordingly.

No changes are permitted in the research without prior approval by ABUTH HREC, except in circumstances outlined in national code for Health Research Ethics: http://www.nhrec.net.

ABUTH HREC reserves the right to conduct compliance assessment visits to your research site without prior notification.

15/02/2018

for **Prof. Aisha. I. Mamman** MBBS, FMCPath

Chairperson