Clinical Trial Details (PDF Generation Date :- Fri, 19 Oct 2018 10:43:32 GMT)

CTRI Number	CTRI/2016/05/006969 [Registered on: 31/05/2016] - **Trial Registered Prospectively**
Last Modified On	23/07/2018
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage in women delivering vaginally
Scientific Title of Study	A phase III, randomized, double-blind, active, controlled, multinational, multicentre, non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally

Secondary IDs if Any

Secondary ID	Identifier
2014-004445-26	EudraCT
A65870, Version no. 1.2.1, 7 March 2016	Protocol Number
ACTRN12614000870651	ANZCTR

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Shivaprasad S Goudar
Designation	KLE Universitys J N Medical College
Affiliation	KLE Univeristys J N Medical College
Address	Womens and Childrens Health Research Unit KLE Universitys J N Medical College Nehru Nagar Belgaum KARNATAKA 590010 India Belgaum KARNATAKA 590010 India
Phone	9448126371
Fax	8312472891
Email	sgoudar@jnmc.edu

Details Contact Person (Scientific Query)

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Name	Dr Shivaprasad S Goudar
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Source of Monetary or Material Support

Source of Monetary or Material Support
> World Health Organization

Primary Sponsor

Primary Sponsor Details	
Name	World Health Organization
Address	Department of Reproductive Health and Research World Health Organization 20 Avenue Appia CH 1211 Geneva 27 Switzerland
Type of Sponsor	Government funding agency

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
Argentina
Egypt
India
Kenya
Nigeria
Singapore
South Africa
Thailand
Uganda
United Kingdom

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Shobha Shiragur	BLDE Universitys Shri B M Patil Medical College Hospital and Research Centre	Smt Bangaramma Sajjan Campus Sholapur Road Bijapur 586103 Bijapur KARNATAKA	9663330846 shiragur1208@gmail.com
Dr Shivaprasad S Goudar	KLE Universitys J N Medical College & KLES Dr Prabhakar Kore Hospital and MRC Belgaum	Nehru Nagar Belgaum 590010 Belgaum KARNATAKA	9448126371 sgoudar@jnmc.edu
D Archana Patel	Lata Medical Research Foundation Nagpur	9/1 Kinkine Kutir Oppsite Hanuman Temple Vasant Nagar Deekshabhoomi Square Nagpur 440022 Nagpur MAHARASHTRA	9823154463 dr_apatel@yahoo.com
Dr Ashalata Mallapur	S Nijalingappa Medical College & Hanagal Shri Kumareshwar Hospital & Research Centre	Navnagar Bagalkot 587102 Bagalkot KARNATAKA	9945699986 drashalatamallapur@gmail.com
Dr Sujata Misra	SCB Medical College Cuttack	Manglabag Cuttack Cuttack	9437094466

		ORISSA	drsujatamisra@gmail.com
Dr Uma Pandey	Sir Sunderlal Hospital Department of Obstetrics & Gynaecolgy Institute of Medical Sciences	Banaras Hindu University Varanasi-221005 Varanasi UTTAR PRADESH	9793094060 uma.pandey2006@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Review Committee Lata Medical Research Foundation-DAGA Memorial Hopsital Nagpur	Approved	23/05/2016	No
Institutional Ethical Committee BLDE Universitys Shri B M Patil Medical College	Approved	17/10/2015	No
Institutional Ethics Committee Institute of Medical Sciences Banaras Hindu University Varanasi	Approved	28/05/2016	No
Institutional Ethics Committee of S Nijalingappa Medical College and Hanagal Shri Kumareshwar Hospital and Research Centre Bagalkot	Approved	25/08/2015	No
Institutional Ethics Committee SCB Medical College Cuttack	Approved	10/05/2016	No
JNMC Institutional Ethics Committee on Human Subjects Research KLESs Jawaharlal Nehru Medical College Belgaum	Approved	23/07/2015	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	25/04/2016

Health Condition / Problems Studied

Health Type	Condition
Patients	Prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally

Intervention / Comparator Agent

Type	Name	Details
Intervention	Carbetocin	Carbetocin Room Temperature Stable (RTS) Dosage: 100 µg solution Route of administration: Intramuscular (IM) Injection Frequency and Total duration: Single dose
Comparator Agent	Oxytocin	Oxytocin Dosage:10 IU solution

			Route of Administration: Intramuscular (IM) Injection Frequency and Total duration: Single dose

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	45.00 Year(s)
Gender	Female
Details	Trial participants will be pregnant women coming to the hospital for delivery. Participants will be eligible for the trial if 1.They are expected to deliver vaginally 2.They have a cervical dilatation equal to or less than 6cm 3.They have a known singleton pregnancy 4.They provide written informed consent before any trial related procedures are carried out

Exclusion Criteria

Exclusion Criteria	
Details	Participants will be excluded from participating in the trial if they are/have 1.In an advanced first stage of labour (>6 cm cervical dilatation) or too distressed to understand, confirm and give informed consent regardless of cervical dilatation 2.Minors 3.Scheduled for a planned caesarean section 4.A birth considered as an abortion according to local guidelines 5.Known allergies to carbetocin, other oxytocin homologues or excipients in the medicinal products used in the trial 6.Known cardiovascular disorders 7.Known hepatic or renal disease 8.Epilepsy 9.Not capable of giving consent due to other health problems such as obstetric emergencies (e.g. antepartum haemorrhage) or mental disorder

Method of Generating Random Sequence	Permuted block randomization, fixed
Method of Concealment	Centralized
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
-The Proportion of women with blood loss of 500 mL or more or the use of additional uterotonics at one hour and up to two hours for women who continue to bleed after one hour -The proportion of women with blood loss of 1000 mL or more at one hour and up to two hours for women who continue to bleed after one hour	1 to 2 hours post-partum

Secondary Outcome

Outcome	Timepoints
The proportion of women with blood loss of 500 mL or more at one hour (or two hours postpartum if the bleeding continues beyond one hour)	1 to 2 hours post-partum
Blood loss in mL at one hour (or two hours postpartum if the bleeding continues beyond one	1 to 2 hours post-partum

hour)	
The proportion of women receiving additional uterotonics at one hour (or two hours postpartum if the bleeding continues beyond one hour)	1 to 2 hours post-partum
The proportion of women receiving additional uterotonics up to time of discharge	Up to the time of discharge
The proportion of women receiving blood transfusion up to time of discharge	Up to the time of discharge
The proportion of women with manual removal of placenta up to time of discharge	Up to the time of discharge
The proportion of women having additional surgical procedures (e.g. suturing of cervix/high vaginal tear, exploration of uterine cavity under general anaesthetic, uterine compression suture, uterine or hypogastric ligation, hysterectomy) up to time of discharge	Up to the time of discharge
The proportion of maternal death	Up to the time of discharge
The proportion of women with composite outcome of maternal death or severe morbidity (admission to intensive care unit, hysterectomy, blood loss of two liters or more, uterine inversion) up to time of discharge	Up to the time of discharge
The incidence and severity of adverse or serious adverse events up to time of discharge	Up to the time of discharge
Newborn outcomes (vital status, APGAR score at 5 minutes, resuscitation of the baby, mechanical ventilation)	At the time of delivery

Target Sample Size	**Total Sample Size=**30000 **Sample Size from India=**7100
Phase of Trial	Phase 3
Date of First Enrollment (India)	01/06/2016
Date of First Enrollment (Global)	07/07/2015
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Completed
Recruitment Status of Trial (India)	Completed

Publication Details	Study Protocol publication details are as below Widmer M, Piaggio G, Abdel-Aleem H, Carroli G, Chong YS, Coomarasamy A, Fawole B, Goudar S, Hofmeyr GJ, Lumbiganon P, Mugerwa K, Nguyen TM, Qureshi Z, Souza JP, Gülmezoglu AM. Room temperature stable carbetocin for the prevention of postpartum haemorrhage during the third stage of labour in women delivering vaginally: study protocol for a randomized controlled trial. Trials. 2016 Mar 17;17(1):143. doi: 10.1186/s13063-016-1271-y. PMID: 26988231 Link to article: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-016-1271-y
Brief Summary	This Phase III study is proposed to show the non-inferiority of carbetocin room temperature stable (RTS) 100 µg intramuscular (IM) versus oxytocin 10 IU IM for preventing postpartum haemorrhage (PPH) in women delivering vaginally. The study will take approximately 24 months to complete and will be performed as a multi-national, double-blind, parallel group study, in accordance with the study protocol. Globally, this study is proposed to be conducted in 10 countries including United Kingdom, South Africa, Uganda, Nigeria, Kenya, Egypt, Singapore, Thailand, Argentina, and India.We propose to conduct the above referenced study on 7100 subjects at 06 study centers in India, out of an approximately 30,000 planned subjects to be enrolled globally.