



Clinical Trial Details (PDF Generation Date :- Mon, 16 Dec 2019 03:35:51 GMT)

<b>CTRI Number</b>	CTRI/2016/05/006969 [Registered on: 31/05/2016] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	07/08/2019	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Drug	
<b>Study Design</b>	Randomized, Parallel Group, Active Controlled Trial	
<b>Public Title of Study</b>	Non-inferiority trial using carbetocin room temperature stable (RTS) for the prevention of postpartum haemorrhage in women delivering vaginally	
<b>Scientific Title of Study</b>	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	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	2014-004445-26	EudraCT
	A65870, Version no. 1.2.1, 7 March 2016	Protocol Number
	ACTRN12614000870651	ANZCTR
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	Dr Shivaprasad S Goudar
	<b>Designation</b>	KLE Universitys J N Medical College
	<b>Affiliation</b>	KLE Univeristys J N Medical College
	<b>Address</b>	Womens and Childrens Health Research Unit KLE Universitys J N Medical College Nehru Nagar Belgaum KARNATAKA 590010 India Belgaum KARNATAKA 590010 India
	<b>Phone</b>	9448126371
	<b>Fax</b>	8312472891
	<b>Email</b>	sgoudar@jnmc.edu
	<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>
<b>Name</b>		Dr Shivaprasad S Goudar
<b>Designation</b>		KLE Universitys J N Medical College
<b>Affiliation</b>		KLE Univeristys J N Medical College
<b>Address</b>		Womens and Childrens Health Research Unit KLE Universitys J N Medical College Nehru Nagar Belgaum KARNATAKA 590010 India Belgaum KARNATAKA 590010 India
<b>Phone</b>		9448126371
<b>Fax</b>		8312472891
<b>Email</b>		sgoudar@jnmc.edu
<b>Details Contact Person (Public Query)</b>		<b>Details Contact Person (Public Query)</b>
	<b>Name</b>	Dr Shivaprasad S Goudar
	<b>Designation</b>	KLE Universitys J N Medical College
	<b>Affiliation</b>	KLE Univeristys J N Medical College
	<b>Address</b>	Womens and Childrens Health Research Unit KLE Universitys J N Medical College Nehru Nagar Belgaum KARNATAKA 590010 India Belgaum



	KARNATAKA 590010 India			
<b>Phone</b>	9448126371			
<b>Fax</b>	8312472891			
<b>Email</b>	sgoudar@jnmc.edu			
<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> World Health Organization			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	World Health Organization			
<b>Address</b>	Department of Reproductive Health and Research World Health Organization 20 Avenue Appia CH 1211 Geneva 27 Switzerland			
<b>Type of Sponsor</b>	Government funding agency			
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	Argentina			
	Egypt			
	India			
	Kenya			
	Nigeria			
	Singapore			
	South Africa			
	Thailand			
	Uganda			
	United Kingdom			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	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 Kumareswar Hospital & Research Centre	Navnagar Bagalkot 587102 Bagalkot KARNATAKA	9945699986 drashalatamallapur@gmail.com
	Dr Sujata Misra	SCB Medical College Cuttack	Manglabag Cuttack Cuttack	9437094466



**Details of Ethics Committee**

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

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Review Committee Lata Medical Research Foundation-DAGA Memorial Hospital 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 Kumareswar 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	Third-stage hemorrhage

**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
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>	
	<b>Age From</b>	18.00 Year(s)
	<b>Age To</b>	45.00 Year(s)
	<b>Gender</b>	Female
	<b>Details</b>	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
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>	
	<b>Details</b>	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
<b>Method of Generating Random Sequence</b>	Permuted block randomization, fixed	
<b>Method of Concealment</b>	Centralized	
<b>Blinding/Masking</b>	Participant, Investigator, Outcome Assessor and Data-entry Operator Blinded	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	-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
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	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 hour)	1 to 2 hours post-partum
	The proportion of women receiving additional	1 to 2 hours post-partum



uterotonics at one hour (or two hours postpartum if the bleeding continues beyond one hour)	
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

<b>Target Sample Size</b>	<b>Total Sample Size=30000</b> <b>Sample Size from India=7100</b> <b>Final Enrollment numbers achieved (Total)=29645</b> <b>Final Enrollment numbers achieved (India)=7098</b>
<b>Phase of Trial</b>	Phase 3
<b>Date of First Enrollment (India)</b>	01/06/2016
<b>Date of First Enrollment (Global)</b>	07/07/2015
<b>Estimated Duration of Trial</b>	<b>Years=2</b> <b>Months=0</b> <b>Days=0</b>
<b>Recruitment Status of Trial (Global)</b>	Completed
<b>Recruitment Status of Trial (India)</b>	Completed
<b>Publication Details</b>	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.