Clinical Trials Registry - India (CTRI)

National Institute of Medical Statistics, Indian Council of Medical Research),
Ansari Nagar, New Delhi -110029 - India,Telephone: 91-11-26588803 91-11-26588803 , 91-11-26588725 91-11-26588725
Fax: 91-11-26589635, Email: ctr.nims[at]gmail.com

http://ctri.nic.in/Clinicaltrials/ViewTrial.jsp?trialno=2783

UTRN.WHO	**TEMP UTRN 101042688-0210201027833847**
CTRI No.and Date	**CTRI/2010/091/001469, 11-01-2011**
Status of TrialWHO	**Not yet recruiting**
Last Verified onWHO	11-01-2011
Last Updated onWHO	05-01-2011
Contact Details:	sreedhar@clinfoxintl.com

IDENTIFIERS

UTRN.WHO*	**TEMP UTRN 101042688-0210201027833847**
Public Title StudyWHO*	A Clinical Trial to study the safety & effectiveness of Adult Stem Cells derived from Bone Marrow via different routes of administration in the treatment of patients with complete Spinal Cord Injury (SCI)
Scientific Title of StudyWHO*	AN OPEN LABEL, RANDOMIZED, MULTICENTRIC, PROSPECTIVE, CLINICAL STUDY TO DETERMINE THE SAFETY AND THEREPEUTIC EFFECTIVENESS OF BONE MARRROW DERIVED ADULT STEM CELLS VIA MULTIPLE ROUTES OF ADMINSTRATION IN THE TREATMENT OF PATIENTS WITH COMPLETE SPINAL CORD INJURY (SCI)
Secondary IDsWHO	**Secondary ID** / **Registry**: CFINTL/HB/CT-II/III/020/14-2010 / Protocol No

CONTACT INFORMATION OF INVESTIGATORS & SPONSORS

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

Principal Investigator's Name	Dr. Himanshu Bansal	Email ID	bansal.drhimanshu@gmail.com
Address line 1	Anupam Hospital	Address line2	Kashipur Road

City	Rudrapur	State	Uttarakhand
Postal Code	263153	Country	India
Telephone No.(with STD code)	05944-243891 05944-243891	Fax No.	
Contact Person (Scientific Query).WHO			
Name of the contact person(Scientific query)	Dr. Himanshu Bansal	Email ID	bansal.drhimanshu@gmail.com
Address line 1	Anupam Hospital	Address line2	Kashipur Road
City	Rudrapur	State	Uttarakhand
Postal Code	263153	Country	India
Telephone No.(with STD code)	05944-243891 05944-243891	Fax No.	
Affiliation			
Contact Person (Public Query).WHO			
Name of the contact person(Public query)	Sreedhar Singamala	Email ID	sreedhar@clinfoxintl.com
Address line 1	Office 14 & 15, First Floor,Soni Business Complex,Prashanthi Nagar	Address line2	
City	Hyderabad	State	Andhra Pradesh
Postal Code	500072	Country	India
Telephone No.(with STD	040-64545858 040-64545858	Fax No.	

code)			

Source/s of Monetary or Material Support[WHO]	**Source/(s) of Monetary or Material Support** ClinFOX International Office 14&15, 1st Floor, Soni Business Complex, Prashanthi Nagar, Kukatpally, Hyderabad-500 072 (India) Phones: 040-64545858 040-64545858 ,64585860
Primary Sponsor[WHO]	Dr. Himanshu Bansal Foundation
Secondary Sponsor[WHO]	**Secondary Sponsor** ClinFOX International
Countries of Recruitment[WHO]	**Countries of Recruitment** India

Details Site/s of study (details of responsible contact person at each site)

Number of Sites	3

Site/s Details

Site Address	Contact Person
Nurture Hospitals	Dr. Anupama Bansal , C-125 , NARAINA VIHAR , New Delhi , New Delhi -110028 , India Tel:+91-8126604942 Email:dr.anupama.bansal@gmail.com
KS Hospitals	Dr. Himanshu Bansal , # 747 Poonamallee High Road , Kilpauk , Chennai , Tamilnadu -600010 , India Tel: 044-26412326 044-26412326 Email:bansal.drhimanshu@gmail.com
Anupam Hospital	Dr.OP Mahajan , Department of Orthopaedic Surgery , Rudrapur , Uttarakhand -263153 , India Tel: 05944243891 05944243891 Email:dr.mahajan.op@gmail.com

REGULATORY APPROVALS

Ethics Committee*

Ethics Committee Name	Approval Status
KS Hospitals-Independent Ethics Committee	Approved

	<table><tr><td>Anupam Hospital-Independent Ethics Committee</td><td>Approved</td></tr><tr><td>Nurture Hospitals-Independent Ethics Committee</td><td>Approved</td></tr></table>
Regulatory Approval obtained from DCGI*	Not Applicable

METHODS

Health Condition/Problems Studied[WHO]	Patients with complete Spinal Cord Injury full filling ASIA level A Scale
Study Type[WHO]	Other

Intervention and Comparator/Control agent[WHO]

Intervention Name	<table><tr><th>Intervention</th><th>Other details(dose, duration, etc)</th></tr><tr><td>Bone Marrow derived Adult Stem Cells</td><td>20 ml of Achieved concentrate from 120ml of aspirate adult stem cells</td></tr></table>
Control Intervention Name	<table><tr><th>Control Intervention</th><th>Other details(dose, duration, etc)</th></tr><tr><td>NIL</td><td>NIL</td></tr></table>
Key Inclusion/ Exclusion Criteria[WHO]	Inclusion Criteria: 1. Be a Male/Female of ages 18 to 65 years 2. Who is properly informed of the nature and risks of the clinical study, who is willing and capable of complying with all clinical study procedures, and has given informed consent in writing prior to entering the clinical study. Subjects who are willing to comply with the study procedure. 3. Be with complete spinal cord injury (ASIA level A) 4. Time between injury and enrollment is greater than or equal 1 month and less than or equal to 1 year 5. Have Platelet count > 100 Thousand/µL at screening 6. Have White Blood Count < 15,000 7. International Normalized Ratio (INR) less than or equal to 1.5 8. Hematocrit < 30% prior to bone marrow aspiration 9. Have the neurological level is between C5 and T10 10. Have complete or partial transaction/damage as shown by MRI Exclusion Criteria: x. Ongoing Alcohol/ Substance Abuse. x. Intoxication, Intubation, Sedation and Immobilization x.Osteoporosis or low bone mass as determined by medical history or DXA x. Cancer over last 3 years prior to enrollment x. Presence of a primary Hematological disease or any coagulation abnormalities or concomitant treatment with coumarin anti-coagulant x. Implanted Medical Devices like Cardiac Stents, Pace Makers, Bladder Stimulators and Permanent modification of Anatomy x. Uncontrolled Diabetes, Hypertension, Auto Immune Disease, Psychiatric illness, terminal

<table>
<tr><td></td><td>Renal Failure with existing dependence on dialysis and history of Bone Marrow diseases x. Possibility of non-compliance with the protocol. x. Subjects with Syringomyelia, Spinal Stenosis, Plexopathy, Neuropathy, Radiculopathy, Cauda Equina Injury, Myelitis, Demyelination, Ischemia, Severe Spinal Degenerative Pathologies, Ongoing Focal Spinal Cord Compression or anatomically complete lesions x.Longitudinal dimension of injury more than 3 segments x. Women who is pregnant or nursing or of child-bearing potential unwilling to use effective barrier method of contraception for the duration of the study x.No informed consent. x. Signs of Meningitis with Fever (above 39°C) x. Coma or other severe injury or disease x. Penetrating injury x. Unsuitable based on MRI or other factor x. Subjects who have taken Immunosuppressant?s within the last one month</td></tr>
<tr><td>Method of generating randomization sequence</td><td>Stratified randomization</td></tr>
<tr><td>Method of allocation concealment</td><td>Sequentially numbered, sealed, opaque envelopes</td></tr>
<tr><td>Blinding and masking</td><td>Open label</td></tr>
<tr><td colspan="2">Primary Outcome[WHO]</td></tr>
<tr><td>Outcome name</td><td>
<table>
<tr><th>Primary Outcome</th><th>Timepoints</th></tr>
<tr><td>To Establish Safety Of Stem Cell Therapy In Patients⎫Safety: Incidence And Severity Of Adverse Events⎫With Complete Spinal Cord Injury Clinical⎫(Assessed Clinically And By Laboratory Assessments) Efficacy: Improvement In The Neurological Function, Functional Capacity By ASIA Level A Clinical Improvement In The Sensory Functions By SSEP/SEPs⎫Score Clinical Improvement In Bladder Function By⎫(Somatosensory Evoked Potential) Urodynamic Studies</td><td>1.5 Years</td></tr>
</table>
</td></tr>
<tr><td colspan="2">Key secondary outcome/s[WHO]</td></tr>
<tr><td>Outcome name</td><td>
<table>
<tr><th>Secondary Outcome</th><th>Timepoints</th></tr>
<tr><td>Evaluation of the changes in the neurological functions via¬ Measurable improvement in the</td><td>2 Years</td></tr>
</table>
</td></tr>
</table>

	performance of¬different route of administration Activities of Daily Living (ADL) using Spinal Cord Independence Measure (SCIM) Reduction in the use¬ Spasticity (using Modified Ashworth Scale (MAS)) ¬Score Changes in Spinal MRI Finding¬of Medicines.		
Target sample size[WHO]	100	Phase of Trial*	Phase 2/Phase 3
Date of first Enrollment[WHO]	09- 02- 2011 [date-month-year]	Estimated duration of trial	02 Years
Status of Trial[WHO]*	Not yet recruiting		
Brief Summary	This study is an open label, randomized, multi centric trial comparing the safety and efficacy via different routes of administration (intrathecal, intravenous, direct) of bone marrow derived adult stem cells in patients with complete spinal cord injury in about 100 patients. In this study, subjects fulfilling the inclusion criteria will be enrolled in the study by taking the ICD, followed by randomization. Bone marrow derived adult stem cells derived from bone marrow aspirate will be administered either intrathecally below the site of lesion, intravenously or directly at the site of lesion. Efficacy will be assessed by clinical assessment of neurological and urinary bladder functions. Safety will be assessed throughout the study.		