Clinical Trial Details (PDF Generation Date :- Tue, 19 Oct 2021 15:03:34 GMT)

CTRI Number	CTRI/2010/091/006143 [Registered on: 11/01/2011] -
Last Modified On	18/02/2013
Post Graduate Thesis	
Type of Trial	
Type of Study	
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Randomised Double Blind Controlled Trial of Minocycline in Japanese encephalitis
Scientific Title of Study	Randomised Double Blind Controlled Trial of Minocycline in Japanese encephalitis

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

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

Details of Principal Investigator	
Name	Rashmi Kumar
Designation	
Affiliation	
Address	Department of Pediatrics CSM Medical University Lucknow UTTAR PRADESH 226003 India
Phone	0522-2322577
Fax	
Email	rashmik2005@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Rashmi Kumar
Designation	
Affiliation	
Address	Department of Pediatrics CSM Medical University Lucknow UTTAR PRADESH 226003 India
Phone	0522-2322577
Fax	
Email	rashmik2005@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Rashmi Kumar
Designation	
Affiliation	
Address	Department of Pediatrics CSM Medical University Lucknow UTTAR PRADESH 226003 India
Phone	0522-2322577
Fax	
Email	rashmik2005@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> National Brain Research Centre, Manesar, Gurgaon

Primary Sponsor

Primary Sponsor Details	
Name	National Brain Research Centre, Manesar, Gurgaon
Address	
Type of Sponsor	

Details of Secondary Sponsor

Name	Address
NIL	

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Rashmi Kumar	Department of Pediatrics	CSM Medical University ,Chowk-226003 Lucknow UTTAR PRADESH	0522-2322577 rashmik2005@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
CSMMU Ethics Committee	Approved	No Date Specified	Not Available

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
	Japanese encephalitis

Intervention / Comparator Agent

Type	Name	Details
Intervention	Minocycline	5 mg/kg followed by 2.5 mg/kg 12 hourly for 7 dauys; 200 mg followed by 100 mg 12 hourly in adults
Comparator Agent	Placebo	same as for drug

Inclusion Criteria

Inclusion Criteria	
Age From	
Age To	
Gender	
Details	Children > 3 years old and adults with suspected encephalitis

Exclusion Criteria

Exclusion Criteria	
Details	women of child bearing age (16-44 years)

Method of Generating Random Sequence	Random Number Table
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
Cumulative Mortality at 3 months from onset	3 months

Secondary Outcome

Outcome	Timepoints
? Number of days since randomization for fever to subside. ? Number of days since randomization to come to oral feeding ? Number	3 months

	of days since randomization to return to full consciousness (Glasgow Coma Scale of 15) ? Number of days in hospital since randomization ? Neurological deficits or abnormalities of tone or posture or movement at discharge. ? Neurologic deficits, frank mental retardation or other symptoms such as epilepsy at follow up at 6 months
Target Sample Size	**Total Sample Size=**144 **Sample Size from India=**72 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 3
Date of First Enrollment (India)	29/08/2012
Date of First Enrollment (Global)	29/08/2012
Estimated Duration of Trial	**Years=**3 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Open to Recruitment
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	
Brief Summary	