

Diary No: 3119
Date: 19.01.18

F. No. 12-01/18-DC (Pt-37)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, New Delhi - 110002 (India)
New Drugs Division

Tele No.011-23236965
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Dated: 06-08-2018

To,
Dr. Chanchal Kumar,
Senior Resident, Department of Neonatology,
JIPMER, Puducherry-605006

Subject: "Magnesium sulfate as an adjunct to therapeutic hypothermia in the management terms infant with hypoxic ischemic encephalopathy, A randomized controlled trial"-regarding.

Reference: Your application diary no. 3119 dated-19.01.18 on the subject mentioned above.

CT NOC No. : CT/ND/33/2018

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the **Protocol No: JIP/IEC/2017/0361, Version 02, dated 18.10.2016** submitted to this Directorate.

Sr. No.	Investigator & Trial site	Ethics Committee Name/Registration Number
1.	Dr. Chanchal Kumar, Senior Resident, Department of Neonatology, JIPMER, Puducherry-605006	Jawaharlal Institute of Postgraduate Medical Education and Research Jipmer Room No. 106 Dean Research Office Administrative Block 1st Floor Dhanvantari nagar Puducherry -605006 India. ECR/342/Inst/PY/2013/RR-16

Kindly note that the clinical trial permission is subject to the following Conditions:

- a) Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.
- b) Approval of Institutional Ethics Committee duly registered with CDSCO (under Rule 122DD of Drugs & Cosmetics Rules) should be obtained and submitted to this Directorate before initiation of the study.
- c) Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study.

- d) Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority.
- e) Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y.
- f) **In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority.**
- g) The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations.
- h) The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, Investigational drugs, etc. Related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.
- i) Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered by Institutional Ethics committees.
- j) The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc.
- k) The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.
- l) In addition to the requirement of obtaining written informed consent, an audio-video recording of the informed consent process in case of vulnerable subjects in clinical trial of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record; provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed

consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record, as per Government of India, Gazette Notification vide G. S. R. no. 611(E) dated 31.07.2015.

- m) The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
- n) It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not conveyor imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted 10 you
- o) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect as per the requirements specified in Appendix V of Schedule Y of the Drugs and Cosmetics Rules, 1945 must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.
- p) Informed Consent Form needs to be modified w.r.t risk of intellectual disability and mortality expected in this trial.**
- q) Issues related to compensation in case of trial related SAE needs to be clearly mentioned in the Informed Consent Document.**

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)