

31381-Institutional review board statement

The study was reviewed and approved by the institutional review boards of Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, India.

INDIRA GANDHI INSTITUTE OF MEDICAL SCIENCES
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Memo No. IGIMS/2014/ २५६ /Acad. Date: 5 /04/2014

To,

Prof. (Dr.) V. M. Dayal,
Professor department of Gastroenterology-cum- Guide

Dr. Sharad Kumar Jha,
DM Student Dept. of Gastroenterology.

Sub:- "Role of Vitamin D Deficiency as a Risk Factor for Mortality in Patients with Decompensated Cirrhosis and effect of Vitamin D Replenishment on the Mortality in these Patients".

Ref: Ethics Sub-Committee Meeting held on 12/03/2014.

Sir,

In reference to your submitted protocol "**Role of Vitamin D Deficiency as a Risk Factor for Mortality in Patients with Decompensated Cirrhosis and effect of Vitamin D Replenishment on the Mortality in these Patients**" following recommendation of Departmental scientific Committee and discussion in Ethics Sub-Committee meeting held on 12/03/2014 the project was approved in its present form. The study was also subsequently ratified by the Chairman Ethics Committee of IGIMS on behalf of Institute Ethics Committee.

You are required to follow the guidelines of ICMR and GCP during conduct of the study and to take DCGI permission if required, before starting the Study.

The Ethics Sub-Committee expects to be informed about the progress of the study on prescribed format every six months. Any SAE (Serious adverse event) occurring in the course of study or thereafter in follow up, must be promptly notified to the Ethics committee within 24 hours of its occurrence. Any change in present Study protocol must be immediately notified to Ethics Sub Committee for necessary approval. This is to certify that the Guide/ Co guide and or the Candidate were not present during decision making.

[Signature]
Member Secretary
Ethics Sub-Committee
Member Secretary
Ethics Sub Committee
IGIMS, Patna-14

[Signature]
Convener (Member Secretary)
Institute Ethics Committee