

This manuscript is based on the contents of MCh Surgical Gastroenterology thesis of one of the co-authors (Shahana Gupta). The Institute Ethics Committee and PG research monitoring committee approval of this thesis are enclosed.



**JAWAHARLAL INSTITUTE OF POSTGRADUATE MEDICAL
EDUCATION AND RESEARCH, PUDUCHERRY - 605006**
(Institution of National Importance under the Ministry of Health and Family
Welfare, Government of India)

Institute Ethics Committee (Human Studies)
Reg.No: ECR/342/Inst/PY/2013

JIP/IEC/SC/2015/13/726

Date: 24.03.15

CERTIFICATE

This is to certify that the project JIP/IEC/SC/2015/13/726, entitled "A retrospective study of pathological changes in splenic vein in patients undergoing shunt surgery for EHPVO and NCPF." submitted by Dr. Shahana Gupta, Senior Resident, Dept. of Surgical Gastroenterology has been approved by the Institute Ethics Sub Committee (Human Studies), at the meeting held on 23-02-2015, under the following terms and conditions.

- a. This approval is valid for three years or the duration of the project whichever is less from the date of the Certificate.
- b. All procedures to be used on participants are professionally acceptable and standardized.
- c. The investigator should ensure that any drug(s) or combination of drugs or new medical device(s) used are approved for marketing or for clinical trial by DCGI, New Delhi.
- d. All adverse events during the study must be recorded and reported to ADR Monitoring Centre, JIPMER
- e. Any serious adverse event occurring during the course of the study should be reported to the IEC within a period of 24 hours.
- f. Any change in the study procedure/site/investigator should be informed to the IEC.
- g. A yearly progress report of the project has to be submitted to the IEC for review.
- h. The process of informed consent should be audio-video recorded for all clinical trials Coming under per schedule Y Rule 122-DAA (DCGI order: F. No. GCT/20/SC/Clin./2013 DCGI dated: 19.11.2013), as applicable.
- i. It is the responsibility of the Investigator of clinical trial to register with "CLINICAL TRIALS REGISTRY - INDIA" (www.ctri.nic.in), as applicable.

(T.K. Dutta)
Member Secretary
Institute Ethics Committee
(Human Studies)
JIPMER

To

Investigator:

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PG Research Monitoring Committee (PGRMC)

Dr. T. S. Ravikumar,
Director, JIPMER

Dr. S. C. Parija
Dean (Research), JIPMER
Chairperson, PGRMC

CERTIFICATE

This is to certify that the PG dissertation proposal with the following details has been approved by the PG Research Monitoring Committee, in the meeting of PGRMC held on **24th October 2014**, subject to clearance of ethics and other committees.

Reg. No. of the Proposal: **PGMRC/MCh/SGE/01/2014**

Title of the proposal: **"A study of association between pathological characteristics of splenic vein and shunt thrombosis in patients undergoing proximal splenorenal shunt for extra hepatic portal venous obstruction."**

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Date: 20/11/2014

Dr. D.M. Thappa,
Member secretary,
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