

Human Research Ethics Committee

Outside Majura Gate, Surat-395 001.

GUJARAT, INDIA

hrec@gmsurat.org



NO.MCS/STU/Ethics Approval/29577/2012. Date:30/10/2012

To,
Dr. K. N. Bhatt,
Professor (Additional) of Medicine,
Department of Medicine,
Government Medical College & New Civil Hospital,
Surat - 395 001, Gujarat.

Dear Dr. K. N. Bhatt,
The "Human Research Ethics Committee has reviewed and discussed the amendment in previously approved protocol of clinical trial entitled "Evolution of efficacy and safety of piperazine-dihydroartemisinin (piperazine-DHA) combination in the treatment of uncomplicated Plasmodium falciparum malaria – a randomized comparative multicentric study" on (15-10-2012).

The following documents were reviewed.

1. Clinical study Protocol (Protocol ID:IPCA/MSD/PHAR/PD-05; Protocol Version Date : 05/03/2012 ; Amendment No. 2.1
2. Investigator Brochure (Version Date : 05/03/2012; Amendment No. 2.1
3. Patient Information Sheet : English, Hindi and Gujarati (Version Date : 05/03/2012)
4. Informed Consent Form: English, Hindi and Gujarati (Version Date : 05/03/2012)
5. Case Record Form (Version Date : 05/03/2012; Amendment No. 2.1)

The following members of the ethics committee were present at the meeting held on 15/10/2012

MEETING ON 15/10/2012

Sr. No.	HUMAN RESEARCH ETHICS COMMITTEE MEMBER'S NAME	Present/ Absent
1	Dr.Pankaj Hiradhar, Ex.,Dean, College Development Council, VNSGU Surat. .	Present
2	Dr.G.R.Patel, Additional Dean, Government Medical College, Surat Surgery Deptt., G.M.C., Surat.	Present
3	Dr.M.K.Vadel, Medical Superintendent, New Civil Hospital, Surat.	Present
4	Dr.R.K.Chavda., Professor & Head , Medicine Department, GMC., Surat.	Absent
5	Dr.N.D.Kantharia, Professor & Head, Pharmacology Department, GMC., Surat	Absent
6	Dr. B.M Jha, Professor & head, Pathology G.M.C, Surat.	Present
7	Dr.J.K.Kosambiya, Asso. Professor, Community Medicine, (PSM) GMC., Surat.	Absent
8	Dr/Sangeeta Trevedi, Addil.Professor, Pediatrics Department, GMC., Surat.	Present
9	Mrs.Shilpa Shah, Legal Expert, (C/o.V.B.Shah, Pediatrics Department, GMC. Surat.	Absent
10	Mr.Bharat Shah : Representative of Non-Government Voluntary agency.(Chhanyado).	Absent
11	Mr.M.S.Rathod, Retired Principal, Social Worker.Surat.	Present
12	Dr.Nimesh Verma, Member Secretary, (Department of Surgery)G..M.C	Present

It is noted that neither you (Principal Investigator) nor any of your proposed study team members were present during the decision making procedures of Human Research Ethics Committee.

We approve the trial to be conducted in its presented form.

The Ethics Committee (Human Research Ethics Committee – Govt. Medical College, Surat) expects to be informed about the annual progress of the study; any SAE occurring in the course of the study in writing, in a week's time from the date of occurrence; any changes in the protocol and patient information sheet/informed consent and asks to provide a copy of the final report.

Yours sincerely,



Member Secretary, Ethical committee
Secretary
Human Research Ethics Committee,
Government Medical College,
Surat.