

Institutional review board statement

Name of Journal: World Journal of Diabetes

Number ID: 02976076

Manuscript Type: Prospective Study

Institutional review board statement: The protocol was approved by the Institutional Ethics Committee (IEC-HR) of the UCMS (University College of Medical Sciences) & GTB Hospital, Dilshad Garden, Delhi, India.

Name: Ashok Kumar Tripathi

Signature:  **Date:** 09/07/2016



INSTITUTIONAL ETHICS COMMITTEE - HUMAN RESEARCH (IEC-HR)
UNIVERSITY COLLEGE OF MEDICAL SCIENCES
UNIVERSITY OF DELHI, DELHI 110095

28th July 2014

Dr Neerja Aggarwal
Department of Medicine
University College of Medical Sciences
Dilshad Garden, Delhi 110095

Subject: To study the role of genetic polymorphisms and epigenetic modifications of renin-angiotensin-aldosterone system on the renoprotective efficacy of ACEI in patients with diabetic nephropathy

Dear Dr Neerja,

The Institutional Ethics Committee for Human Research has reviewed your research proposal entitled "*To study the role of genetic polymorphisms and epigenetic modifications of renin-angiotensin-aldosterone system on the renoprotective efficacy of ACEI in patients with diabetic nephropathy*" in its meeting held on 19th May 2014.

Supervisor Dr OP Kalra

Principal Investigator

Dr Neerja Aggarwal

The following observations were made by the IEC-HR during the initial review process,

1. PIS was not available with the proposal. It should contain information for the patients in locally understandable language and provide information to the participants to improve awareness.
2. It was felt that the Hindi translations provided for PIS and ICF are unclear and poorly done. The translation has changed the meaning of the documents and a considerable improvement is needed in these documents. The hindi documents should be drafted in such a manner that the patient is able to understand the document provided. It should be drafted in the local language that is used for communication in day to day practice and not translated out of a dictionary with words that can not be understood.
3. Number of references needs to be limited

The documents submitted by you in response to the above comments of the committee have been reviewed and found satisfactory. The revised decision after review is "Approved in present form"

We request you to please note the following during the conduct of your study,

1. The study should be conducted as per the plan submitted. Any change in the plan or deviation from methodology must be conveyed to the IEC-HR for consideration
2. Complete confidentiality of data should be maintained
3. Progress reports: Please submit yearly progress reports detailing the work done in your project

4. Completion report: Please submit the final report to the office of the IEC-HR after completion of work
5. Soft Copy Submission: Please forward a soft copy of your proposal if not already done to iechrucms@gmail.com. Please include your name and department in the subject line. Suppose your name is X and you are from the Department of Y, then the subject of your mail should read 'X, Y'. Please do not write anything else in the subject line
6. The members of IEC-HR would randomly review some of the ongoing research projects and you may be requested to submit the documents related to your work to the office of the IEC-HR. We would be glad if you cooperate in the review process with the members of the IEC-HR

Please feel free to contact us in case of any clarifications. We wish you good luck with your research

Yours sincerely



Ashish Goel
(Member Secretary, IEC-HR)