AMRITA VISHWA VIDYAPEETHAM
Institute of Medical Sciences
Healthcare, Education & Research
Institutional Ethics Committee
Reg. No. - ECR/129/Inst/KL/2013/RR-19

Dated 16-12-2021
IEC-AIMS-2021-PHARM-338

To
Ms. Haripriya PS,
Amrita School of Pharmacy, AIMS.

The Institutional Ethics Committee meeting was held virtually on 11-12-2021 at 2.00 pm with Dr. P Mohan Nair as chairman. The following members attended the meeting:

Attendees:

Dr. P Mohan Nair	- Chairman
Dr. Shantikumar V Nair	- Member Secretary
Mr. P R Ajith Kumar	- Legal Expert
Dr. Subramania Iyer	- Clinician
Dr. Dilip Panikar	- Clinician
Dr. Unnikrishnan K Menon	- Clinician
Dr. Subhakumari K N	- Basic Medical Scientist
Mr. Sreehari R	- Social Scientist
Ms. Anjana Balakrishnan	- Legal Expert
Mr. Prahlad Prabhakaran	- Lay Person

The Ethics Committee reviewed the documents pertaining to the study protocol titled "Memantine for the prevention of radiation induced cognitive dysfunction in Brain Metastatic Patients; A Randomized Placebo-Controlled Trial" presented by Ms. Haripriya PS as researcher with Dr. M P Narmadha, School of Pharmacy and Dr. Debnarayan Dutta, Dept. of Radiation Oncology, AIMS.

The study is a single blind, placebo controlled randomized clinical trial with the primary objective to determine whether the addition of memantine in radiotherapy for brain metastasis preserve the cognitive function at 6 months compared to a placebo. Clarification on the standard of care was sought by the Ethics committee members. PI clarified that Memantine is FDA approved and is standard of care in US. It is understood that memantine is DCGI approved and used by some hospitals in India. But, the study of the same is not done on Indian population and therefore this pilot study is conducted to understand its effects on Indian population.

After reviewing the protocol and hearing the Principal Investigator, the Committee finds that the study is in academic and public interest. There are no legal and ethical issues involved in the study. Approval granted. PI to ensure that expenses exclusively relating to the study, if any, shall not be passed on to the subjects. PI to ensure that the study results are not used for promotional purposes.

Investigators to ensure that Reports/Publications do not contain details capable of identifying any of the subjects. A copy of the duly executed informed consent be furnished to the Dean's Office for the purpose of record. The study shall be registered with CTRI.

It is mandatory that Investigators shall submit an interim report at 6 month intervals about the progress of the study and a detailed final report upon closure of the study to the Ethics Committee.

Sincerely,

Amrita Institute of Medical Sciences & Research Centre, Kochi 682041
Institutional Ethics Committee

Dr. P Mohan Nair
Chairman

cc: IEC, AIMS, Kochi

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