



SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH

(A Deemed to be University declared under Section 3 of UGC Act 1956)

Comprising Sri Devaraj Urs Medical College

[Constituent unit of Sri Devaraj Urs Educational Trust for Backward Classes (Regd.)]

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Letter of Association

Date: 08.12.2021

Project Title: 'Nutritional management of hypoalbuminemia in preventing progression of cirrhosis to hepatorenal syndrome'

Preamble: The collaborating institutions are Sri Devaraj Urs Academy of Higher Education (SDUAHER) Tamaka Kolar, a deemed to be University and M S Ramaiah Hospitals, Bangalore. This letter of Association facilitates the collaboration between these two institutes for the purpose of academics and doctoral research activities. The Department of Clinical Nutrition and Dietetics, SDUAHER has planned to conduct a doctoral research with a proposal titled, "Nutritional Management of Hypoalbuminemia in preventing progression of cirrhosis to hepatorenal syndrome" in association with the Department of Gastroenterology, M S Ramaiah Hospitals.

Investigators:

Ms. Shobha, Clinical Dietitian, PhD research scholar, Department of Clinical Nutrition and Dietetics, SDUAHER, Dr. M Madhavi Reddy, Professor and HOD Department of Clinical Nutrition and Dietetics, SDUAHER, Dr. Prabhakar, Professor, Department of General Medicine, SDUAHER and Dr. Nitin Rao, Professor and Surgical Gastroenterologist, Department of Surgical Gastroenterology, M S Ramaiah Hospitals.

The doctoral research project is proposed by Ms. Shobha for the purpose of obtaining her Ph.D. degree and her expertise is in the area of clinical nutrition. The literature review and project synopsis for the proposed study was carried out by Ms. Shobha with the support of guide Dr. M Madhavi Reddy, Co-Guide Dr. Prabhakar and external expert Dr. Nitin Rao, who has proposed improvement to the ideas, specifically with regard to population inclusion, literature review and study methodology. Finally, after discussions involving all the three investigators and the doctoral

research advisory committee, the proposal has been developed to the current format. It has been planned and agreed by all three investigators to recommend and carry out this proposal research work.

Project summary:

In this work, the research scholar will be studying to understand the effect of nutrition support on serum albumin levels in preventing progression of cirrhosis to hepatorenal syndrome in hepatic cirrhosis patients with low serum albumin levels, the time required to improve serum albumin, and quality of life. A standard diet and a peptide based protein formula will be used for the nutritional intervention in cirrhosis patients who have hypoalbuminemia and risk of hepatorenal syndrome. This proposed research is a randomized control trial, hence the study would be conducted after the institutional ethical committee's clearance and it will be registered in the Clinical Trials Registry India. The nutritional intervention in cirrhotic patients will be done for a period of 4 months and a follow up period of 6 months.

The study also involves collection of laboratory and diagnostic data, at baseline, twice during intervention and follow ups. These data collection will be done with the support of the central laboratory and diagnostics present in the institutional campus for convenience of the patients and the investigators with prior informed consent and permissions. The expenses involving the diet, labs and diagnostics will be borne by the research grants.

Roles and Responsibilities:

Ms. Shobha (PI): Primary role in implementation of design and optimization of standard diet and study diet with peptide based formula, recruitment of study population, conducting and intervention, follow ups and collection of data. Dr. M Madhavi Reddy (Guide), Dr. Prabhakara K (Co-guide) and Dr. Nitin Rao (External Expert) : Primary role of the guide and expert will be in coordinating and guiding the doctoral research scholar through every single step of the research and ensure the research work is carried out without any quality compromise and bias as per RCT protocols, ethical interests, and also ensure timely completion of research project.

Probable Outcomes:

The study is recommended as a need to improve nutritional status of cirrhosis patients, hence expected outcomes include reducing incidences of malnutrition, sarcopenia and hepatorenal syndrome. This study can shed light on how optimum nutrition can support in preventing progression of cirrhosis and its associated complications, and improve quality of nutrition life.

All four investigators shall be the investigators ethically and the mother institution, SDUAHER (as per the prevailing institutional IPR guidelines) shall be the owner of the research work. All IPR

issues will be as per the prevailing institutional guidelines mutually agreed upon.

The authorship credits of publications that come as a result of this work will be decided based on mutual agreement, as per the international authorship guidelines.

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