Clinical trials on the goodness of coconut

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Coconut and coconut based products have been a part of traditional medicine from ancient times and was used as oilment in all kinds of illness. But the lack of proper documentation has paved the way for loss of valuable ancient medicinal knowledge wherein coconut or coconut oil was an ingredient. In addition to this, there has been propaganda against the consumption of coconut oil due to its saturated fat content. The use of coconut and coconut oil and its various effects have been one of the long debated issues of the health sector. It is also a known fact that coconut water has been used as an intravenous hydration fluid when medical saline was not available. However research on the benefits of intake of coconut and coconut products are not many. It is in this context that clinical studies on coconut and coconut based products are of relevance which would benefit the coconut sector in a positive way.

Clinical trials play a vital role in the development of new treatments or in the use of new medicines. Now clinical trials and laboratory studies are taken up to verify the effectiveness and to prove the claimed effect of the newly developed product before launching in the market. Such trials are needed for assessing the side effects if any. Clinical trials are only a part of the research that goes into developing a new treatment. Once a new medicine is discovered it has to be tested in labs (in cell and animal studies) before reaching human clinical trials. Due to this reason, from among the thousands of potential drugs tested only a few reaches up to the level of clinical trials.

Another issue in completing the study is the shortage of people who can take part in such trials. In most cases, the sample to be selected is a subset of population with definite characteristics. Obtaining the appropriate group with their consent is yet another barrier. All studies involving a medical or therapeutic intervention on patients must be approved by a supervising ethics committee before permission is granted to run the trial. Clinical trials are only done under the close supervision of appropriate regulatory authorities

Most of the clinical trials are designed to answer two basic questions *i.e.* whether the newly developed treatment or medicine is effective for humans and whether this is safe to humans.

Types of Clinical trials

Clinical trials can be of two types based on the way the researchers behave i.e. they can be just an observational study or it can be interventional study. In an observational study, the investigators observe the subjects and measure their outcomes. The researchers do not actively manage the study. In an interventional study, the investigators give the research subjects a particular medicine or other intervention. Usually, they

compare the treated subjects to subjects who receive no treatment or standard treatment. Then the researchers measure how the subjects' health changes.

Clinical trials can be classified based on their purpose or also whether the trial design allows changes based on data accumulated during the trial.

In India, since 15th June 2009, trial registration in the Clinical Trials Registry-India (CTRI) has been made mandatory by the Drugs Controller General (India) (DCGI) (www.cdsco.nic.in). Any research which involves trial involving human participants, of any intervention such as drugs, preventive measures, lifestyle modifications, etc. as well as trials being conducted in the purview of the Department of AYUSH (http://indianmedicine.nic.in/) is expected to register the trial in the (CTRI) before enrollment of the first participant. Trial registration involves public declaration and identification of trial investigators, sponsors, interventions, patient population etc before the enrollment of the first patient. Submission of ethics approval and DCGI approval (if applicable) is essential for trial registration in the CTRI. Multi-country trials, where India is a participating country, which have been registered in an international registry, are also expected to be registered in the CTRI. In the CTRI, details of Indian investigators, trial sites, Indian target sample size and date of enrollment are captured. After a trial is registered, trialists are expected to regularly update the trial status and all updates and changes will be recorded and available for public display.

Of late, researchers are taking up clinical studies on coconut, coconut oil, virgin coconut oil, coconut water and other coconut products such as haustorium, Neera etc. as there is a lot of debate on the subject. Recently media reports on a study by Dr. Mary Newport, who used coconut oil for treatment of Alzheimer's disease for her husband was in the limelight and has caught the attention of the medical world. Most of the recent investigations conducted in animals and human beings show that coconut oil does not increase the risk of atherosclerosis and heart diseases. Studies have been taken up to compare the effects of virgin coconut oil as a therapeutic moisturizer for ailments such as xerosis. Reports are available stating that kernel protein has cardio protective effect against isoproterenol induced myocardial infarction which may be due to high content of L-Arginine.

Some of the clinical evidences have been already published in reputed scientific journals and the following link: http://coconutresearchcenter.org/Coconut%20Research-Coconut%20Research%20Center.pdf would give a sample of many published studies on coconut.

Coconut Development Board has sponsored research studies under the scheme 'Technology Mission on Coconut' which involves clinical and animal model trials to study the beneficial effects of coconut.

Extensive studies were also taken up by the Department of Biochemistry, University of Kerala in humans and experimental animals to find the effect of coconut in health and diseases. Human studies has brought out that consumption of coconut kernel was found beneficial on blood cholesterol levels and coconut kernel in normal diet alleviated hyperglycemia hyperlipidemia and lipid peroxidation in diabetic condition. Studies on tender coconut water revealed that it has significant hypocholesterolemic, antioxidant, antithrombotic and cardio protective effects. Most of the studies need to go further into human clinical studies and are on the way.

National Institute of Nutrition, Hyderabad has sponsored a project Dietary Coconut Oils (VCO&CO) and their Health Implications. The objective of the project was to evaluate the impact of chronic consumption of diets prepared with coconut oil / virgin coconut oil on lipid metabolism, insulin resistance and inflammatory parameters of young adult healthy human volunteers. The major observations made under the above study are: a) Body composition including body weight and anthropometric data showed no significant changes upon either coconut or virgin coconut oil based diet consumption in normal or over weight subjects respectively b) VCO feeding resulted in elevated plasma HDL-C levels without rise in total cholesterol levels. In overweight

subjects, VCO consumption had elevated plasma HDL-C levels in them altering with cholesterol levels, which is a favorable trend.

One of the pioneer institutes in Medical research, Amrita Institute of Medical Sciences,(AIMS) Kochi is also carrying out specific research on coconut oil, VCO etc. The Department of Cardiology had been entrusted with a study which compared the impact of coconut oil with sunflower oil titled Impact of Coconut Oil as a cooking medium on cardiovascular risk factors and clinical outcomes in patients with coronary artery disease with polyunsaturated sunflower oil. The study has concluded that as a cooking media, even though rich in saturated fatty acids, coconut oil seems to be safe in those receiving standard medical care.

AIMS , Kochi is initiating another study titled Effect of Virgin coconut oil as a dietary supplement on lipid profile and oxidative stress in dislipidemic individuals with low High density lipoproteins[HDL] -A six months follow up study in patients with and with out Coronary Artery Disease with the primary objectives of assessing the HDL raising and LDL lowering property of virgin coconut oil, to assess the antioxidant property of virgin coconut oil and to assess the influence of virgin coconut oil on Apolipoproteins. The present study is designed to evaluate the effect of virgin coconut oil on low HDL and antioxidant activity.The study design could consists of two groups. Group one consists of established case of Coronary artery disease with low HDL on medication and group two consist of normal population with low HDL and no established coronary artery diseases.

Amrita Vishwa Vidyapeetham, Coimbatore has initiated a project on virgin coconut oil as a neuro regenerative agent for Alzheimer's disease-Computational analysis Pharmacogenomic study, which is the first of its kind from India. The primary objective of the study is to identify and characterize genes and proteins responsible for Alzheimer's disease (AD).

Amrita School of Pharmacy, Kochi has initiated a research to identify the benefits of Neera and Neera based products giving emphasis to medicinal and nutritional properties of Neera, Neera sugar and Honey. Neera being a nutraceutical drink, there is a need to have solid and authentic evidence to support the claims. Experiments are being taken up in animal models initially and human clinical trials are also on the way.

Continuous and concerted efforts are to be taken up in medical research world wide to identify and bring forth the benefits of intake of coconut and coconut products. Researchers in India need to be more focused. In the present health conscious world, it is the need of the hour to rediscover the goodness of Kalpavriksha and to bring into light the umpteen therapeutic benefits of coconut.

Research projects on Health benefits of Coconut and coconut based products aided by CDB under TMOC.

Sl No.	Name of project	Institute/ Agency
1	Dietary coconut Oils (VCO & CO) and their health implications-	National Institute of Nutrition (ICMR) Jamai-Osmania, Hyderabad,
2	Impact of Coconut Oil as a cooking medium on cardiovascular risk factors and clinical outcomes in patients with coronary artery disease receiving standard medical care; A randomized case controlled study with polyunsaturated sunflower oil	Department of Cardiology, Amrita Institute of Medical Sciences and Research Centre, Kochi
3	Development of Processes and Herbal formulations based on Virgin Coconut Oil	AVT Institute for Advanced Research (AVTAR), Coimbatore
4	A pilot study on development of a nutraceutical preparation using nut water	Amrita school of Phar macy, AIMS, Ponekkara
5	Development of Technology for Production of Health Foods from Tender & Mature Coconut	Department of Lipid Science & Traditional Foods, CFTRI, Mysore
6	Development of Nutra coconut o il rich in ω-3 & ω-6 fatty acids and health protective phytoceuticals	CFTRI, Mysore
7	Development of a litholytic formulation, incorporating the medicinal properties of coconut water and core of pseudo stem of plantain tree	CARe -Keralam Ltd., Thrissur
8	Immunostimulation with Virgin Coconut Oil to treat recurrent infections of the upper respiratory tract of Children	CARe -Keralam Ltd., Thrissur
9	Development of an Anti Diarrhoeal formulation, incorporating the medicinal principles of coconut water and heart wood of Caesalpinia sappan	CARe -Keralam Ltd., Thrissur
10	Value added formulation of Ayurveda drug Ksheerabala by using Virgin Coconut Oil and its Therapeutic effects on Arthritis	St. Thomas College, Pala, Kottayam
11	Diversified product deve lopment - functional dietary and food ingredient from coconut milk powder	Olive Life sciences Pvt Ltd.,R & D Centre, Karnataka
12	Health benefits of dietary intake of Virgin coconut oil on neural-immune network	School of Bioengineering, SRM University, Ka ttankulathur- Tamil Nadu
13	Development of concentrated extract of Vyosakatvivaradi (VKV) formulation in VCO and evaluation of its genotoxic and carcinogenic effects	AVP Research Foundation Ramanthapuram Coimbatore
14	Isolation, characterization and evaluation of in vitro anti - cancer and antioxidant activities of polyphenols from kernel and oil from coconut	School of Bio Sciences, MG University, Kottayam