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Effects of different forms of coconut on lipid profile

Submission date
31/08/2023

Recruitment status
No longer recruiting

Registration date
08/09/2023

Overall study status
Completed

Last Edited
04/10/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The contribution of dietary fat intake towards atherosclerosis (narrowing of the arteries) is currently generating much debate and a clear association between dietary saturated fat and ischemic events including death has not been established so far. Foods consumed by the general populace are complex and would not contain fatty acids or any other nutrient in isolation and different saturated and unsaturated fatty acids could possibly give rise to different effects on lipid chemistry. Hence the clinically relevant effects of saturated fats derived from different origins could well be different. It is found that coconut fats account for about 80% of the fat intake among Sri Lankans of which 92% consists of saturated fats. Some say that coconut fat may increase the risk of ischemic heart disease among Sri Lankans. However, since saturated fats in coconut are medium-chain fatty acids and do not undergo degradation and re-esterification processes, the hypothesis that coconut fat is bad for health may be questionable. Although coconut oil increases HDL levels, no clear evidence exists to date to claim that coconut oil reduces the risk of atherosclerotic heart disease. As coconut milk contains a significant arginine-rich protein content and also soluble fiber, the lipid effects may be compounded by these dietary elements as well and the effect observed on the lipid profile may not be entirely due to the fatty acids. Coconut is consumed by the vast majority of people in many Asian countries. It is therefore important to investigate the relationship between the lipid profile and coconut consumption. The aim of this study is to investigate the lipid effects of different forms of coconut, i.e., oil, milk, and flakes, when consumed by free-living healthy subjects.

Who can participate?
Healthy volunteers aged 25-60 years

What does the study involve?
The participants are randomly allocated to one of three dietary supplementations: coconut milk powder (30 g), grated coconut (30 g) or coconut oil (30 ml), or a control group (no supplementation). The coconut supplements had different calorie, fat, fiber, and protein content. Participants are instructed to take the allocated supplement for 4 weeks and maintain a daily dietary diary to ensure that their diet does not vary significantly. Body Mass Index (BMI), lipid profile, fasting blood sugar (FBS) and HbA1c are measured three times (baseline and after 4 and 8 weeks).

What are the possible benefits and risks of participating?
There are not any significant health risks or any other risks associated with this study. The results could help raise awareness of the effects of different forms of coconut on the liver.

Where is the study run from?
Medical Research Institute, Colombo (Sri Lanka)

When is the study starting and how long it is expected to run for?
April 2013 to June 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ruvan Ekanayake, Ruvan_nishali.ekanayaka@yahoo.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Ruvan Ekanayaka

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CLPRCT2

Study information

Scientific Title
Effect of different forms of coconut on the lipid profiles of healthy free-living Sri Lankan subjects

Acronym

ECLPSL

Study objectives
Different forms of coconut preparations have different effects on lipid profile

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/03/2014, Ethics Review Committee, Medical Research Institute (PO Box 527, Sir Danister de Silva Mawatha, Colombo 8, 00900, Sri Lanka; +94 (0)112693532; ethicsmri@gmail.com), ref: 02/ 2016 (Project number 43/2013)

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Lipid profile

Interventions
A randomized, placebo-controlled, prospective clinical trial was conducted at the Institute of Medical Research (MRI), Colombo, Sri Lanka. Participants were recruited from a local advertisement displayed in the Medical Research Institute, Colombo, Sri Lanka. A comprehensive medical history was obtained, and a physical examination of the subjects who volunteered was done before recruiting. A random number between 1 and 4, taken from a table of random numbers, was assigned to each consented participant. The participants were randomly allocated to one of three dietary supplementation regimens: coconut milk powder 30 g, grated coconut 30 g or coconut oil 30 ml, or the control group. The coconut supplements were not equi-caloric and had different fat, fiber, and protein content. Each participant was instructed to take the allocated supplement for 4 weeks and was asked to maintain a daily dietary diary to ensure that the diet did not vary significantly. Fasting Blood Sugar (FBS) and HbA1c were measured three times: i.e., baseline, after 4 weeks and 8 weeks. BMI was measured by a single research assistant and all laboratory tests were done by a single technician. Lipid profiles were done after 10 hours of mandatory fasting and FBS was done after 8 hours fast. Total cholesterol, HDL-cholesterol and triglyceride concentrations were measured in serum by a Roch/Hitachi Modular P Chemistry Analyzer (Mod P). The cholesterol assay used the cholesterol oxidase/peroxidase (CHOD/POD) method. HDL cholesterol was measured by a direct non-precipitating method using polyethylene glycol-coupled cholesteryl esterase (PEG-modified enzyme) and cholesterol oxidase. Triglycerides were analyzed using the glycerokinase/glycerophosphate oxidase method after initial hydrolysis with lipoprotein lipase. LDL cholesterol was calculated using the Friedewald formula. FBS and HbA1c were measured by using Abbott’s Diabetes Care FreeStyle Libre.

Intervention Type
Supplement

Primary outcome(s)
1. Lipid profile (consisting of total cholesterol, HDL cholesterol, LDL cholesterol, triglyceride concentrations) measured at baseline and after 4 and 8 weeks. Lipid profiles were done after 10 hours of mandatory fasting and FBS was done after 8 hours fast.
1.1. Total cholesterol, HDL-cholesterol and triglyceride concentrations measured in serum by a Roch/Hitachi Modular P Chemistry Analyzer (Mod P)
1.2. The cholesterol assay used the cholesterol oxidase/peroxidase (CHOD/POD) method
1.3. HDL cholesterol was measured by a direct non-precipitating method using polyethylene glycol-coupled cholesteryl esterase (PEG-modified enzyme) and cholesterol oxidase
1.4. Triglycerides were analyzed using the glycerokinase/glycerophosphate oxidase method after initial hydrolysis with lipoprotein lipase. LDL cholesterol was calculated using the Friedewald formula.

Key secondary outcome(s))
Fasting blood sugar (FBS) and HbA1c measured using Abbott's Diabetes Care FreeStyle Libre at baseline, after 4 weeks and 8 weeks

Completion date
08/06/2017

Eligibility

Key inclusion criteria
1. Healthy volunteers aged 25-60 years
2. Total cholesterol level ≤250 mg/dl
3. Triglyceride level ≤300 mg/dl
4. Not on any form of medication or on nutritional supplementation

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
60 years

Sex
All

Total final enrolment
190

Key exclusion criteria

1. Total cholesterol level ≥250 mg/dl
2. Triglyceride level ≥300 mg/dl
3. On any form of medication or nutritional supplementation

Date of first enrolment
01/04/2014

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Sri Lanka

Study participating centre
Medical Research Institute
PO Box 527, Sir Danister de Silva Mawatha
Colombo
Sri Lanka
00900

Sponsor information

Organisation
Medical Research Institute

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
1. The datasets generated during and/or analysed during the current study will be available upon request from Dr Ruvan Ekanayake (Ruvan_nishali.ekanayaka@yahoo.com).

2. The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication

The SPSS data file of the participants contains age, gender, BMI and measurements of lipid profile (consisting of total cholesterol, HDL cholesterol, LDL cholesterol, triglyceride concentrations), Fasting Blood Sugar (FBS) and HbA1c that were done 3 times: i.e., baseline, after 4 weeks and 8 weeks, will be shared. Consent was obtained from all the participants.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/02/2024	04/10/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes