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Possible reduction of Blood Sugar and Cholesterol from using a blend of rice bran oil and sesame oil in comparison with soybean oil

Submission date
02/02/2019

Recruitment status
No longer recruiting

Registration date
11/02/2019

Overall study status
Completed

Last Edited
16/06/2021

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Research proved that maintaining normal blood glucose and cholesterol levels reduce the death risk compared to those with uncontrolled or poorly controlled levels. The increasing incidence of type-2 diabetes mellitus and the prevalence of high cardiovascular risk emphasizes the need for appropriate lifestyle modifications including dietary modifications which is perceived as a critical addition to the pharmacological intervention for preventing and treating these conditions.
Food habits of individuals have a significant impact on these parameters. Use of various cooking oils has shown to affect the sugar and cholesterol levels. Rice bran, the brown outer layer of rice kernel, contains appreciable quantities of nutrients like protein, fat and dietary fibre and minerals like potassium, calcium, magnesium and iron. Rice bran contains 15-22% oil by weight which contains beneficial fatty acids. Similarly, sesame oil has been used as an important ingredient in cooking worldwide.
Recently, both rice bran oil and sesame oil have attracted the attention of the global scientific community for their beneficial effects in lowering blood sugar and cholesterol levels. Hence it can be presumed that regular consumption of these cooking oils can mitigate the risk of heart attacks and complications arising from diabetes.
Based on this background, the present study was planned to investigate the effect of blended rice bran oil with sesame oil (in 80:20 ratio) as cooking oil medium on changes in blood glucose and cholesterol levels in comparison to soybean oil in type-2 diabetes patients.

Who can participate?
Individuals with diabetes, pre-diabetes (those who are prone to have diabetes) and healthy ones of either gender between ages 25-65 years were included in the present study.

What does the study involve?
The study was initiated after obtaining due approval from the institute ethics committee. The study participants were screened for eligibility in the endocrinology outpatient department. Written consent was obtained from the participants willing to take part in the study. The study participants were categorised into three groups (i.e. Diabetic, Non-diabetic and Pre-diabetic) The Diabetic group was assigned to receive either blended rice bran oil with sesame oil or

soybean oil as cooking oil medium for 12 weeks. Strict confidentiality was maintained throughout the study period. The oils were supplied as coded identical packs. Neither the study participants nor the study personnel were aware of the type of oils supplied to the participants
The non-diabetic and pre-diabetic subjects were given blended rice bran oil with sesame oil only for 12 weeks for the whole family.
The quantity of oil supplied was based on the Indian Council of medical research (ICMR) recommendation on per day consumption of dietary oil.
All participants had 3 follow-up visits at 4-week intervals. Laboratory investigations were done at each follow-up visit.

What are the possible benefits and risks of participating?
Participants received free consultation and laboratory investigation. Additionally, they received cooking oil for the whole family for the entire study duration. Blended rice bran oil with sesame oil and soybean oil are approved by the Government of India and are available in the market and used by consumers. Hence their health-related risk appears negligible.

Where is the study run from?
The study was conducted in a single centre at All India Institute of Medical Sciences, Bhubaneswar, India.

When is the study starting and how long is it expected to run for?
The study was initiated on 21st March 2018 and completed on 12th January 2019.

Who is funding the study?
M/s. PharmaInstinct, a contract research organisation based at Chandigarh, India.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RBSO/10/2017 (ver-2)

Study information

Scientific Title
Possible anti-diabetic and anti-hyperlipidemic efficacy of blended rice bran oil with sesame oil in comparison with soybean oil: a clinical investigation in pre-diabetic and diabetic individuals

Study objectives
To investigate the effect of blend of rice bran oil and sesame oil (80: 20) as cooking oil medium on the change in the glycemic profile and insulin resistance in comparison to soybean oil in type-2 diabetes patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/01/2018, Institutional Ethics Committee (All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar, 751019, India; +91(0)674 2476083; iec.aiimsbbsr@gmail.com), ref: T/EM-F/Pharma/17/24

Study design
Randomized, double blind, 4 armed and parallel group clinical trial.

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional file.

Health condition(s) or problem(s) studied
1. Type-2 Diabetes
2. Pre Diabetic
3. Non-diabetic

Interventions
Three groups of study participants (i.e. Diabetic, Non-diabetic and Pre-diabetic) were screened from the endocrine OPD of the hospital. The Diabetic group was randomized to receive either blend of rice bran oil and sesame oil (80: 20) or soybean oil as cooking oil medium for 12 weeks. Thus in this study group, the active intervention was the blended rice bran oil plus sesame oil (80: 20) and soybean oil was the control group.
The oil packs were identical and coded. The codes were not available to anyone involved in the trial.
Randomization schedule was generated using computer software. The randomization scheme was not made available to the hospital staff, study monitors and other designated individuals at the study site. The codes were broken after the last follow-up visit i.e. after study completion.
Non-diabetic and pre-diabetic subjects were given blend of rice bran oil and sesame oil (80: 20) only.
All participants had 3 follow-up visits at 4 week intervals. Laboratory investigations were done at each follow-up visit.

Intervention Type
Other

Primary outcome measure
1. Fasting Blood Glucose (FBG) measured at baseline, 4 weeks, 8 weeks, and 12 weeks
2. Postprandial Blood Glucose (PPBG) measured at baseline, 4 weeks, 8 weeks, and 12 weeks
3. Haemoglobin A1C (HbA1C) measured at baseline and 12 weeks

Secondary outcome measures
1. Body weight measured at baseline, 4 weeks, 8 weeks, and 12 weeks
2. Height measured at baseline, 4 weeks, 8 weeks, and 12 weeks
3. Systolic Blood Pressure (SBP) measured at baseline, 4 weeks, 8 weeks, and 12 weeks
4. Diastolic Blood Pressure (DBP) measured at baseline, 4 weeks, 8 weeks, and 12 weeks
5. Total Cholesterol (TC) measured at baseline and 12 weeks
6. Low density Lipoproteins (LDL) measured at baseline and 12 weeks
7. Very Low density Lipoproteins (VLDL) measured at baseline and 12 weeks
8. High Density Lipoproteins (HDL) measured at baseline and 12 weeks
9. Serum Triglycerides (TG) measured at baseline and 12 weeks
10. Aspartate Aminotransferase (AST) measured at baseline and 12 weeks
11. Alanine aminotransferase (ALT) measured at baseline and 12 weeks
12. Alkaline Phosphatase (ALP) measured at baseline and 12 weeks
13. Seum Bilirubin measured at baseline and 12 weeks
14. Serum Urea measured at baseline and 12 weeks
15. Serum Creatinine measured at baseline and 12 weeks
16. Serum Uric acid measured at baseline and 12 weeks

Overall study start date
21/03/2018

Completion date

12/01/2019

Eligibility

Key inclusion criteria
1. Patients with Diabetes
1.1 Men and women age 25 to 65 years
1.2 Fasting blood glucose more than 125 mg/dL or HbA1c more than 6.5
1.3 On stable oral anti-diabetic therapy for past 4 weeks or more
1.4 Willing to give informed consent
1.5 Number of adult family members less than 5

2. Subjects with pre-diabetes
2.1 Men and women age 25 to 65 years
2.2 Fasting blood glucose more than 100 and less than 125 mg/dL or HbA1c between 5.7 - 6.5
2.3 Willing to give informed consent
2.4 Number of adult family members less than 5

3. Healthy Volunteers
3.1 Men and women age 25 to 65 years
3.2 Fasting Blood Glucose less than 100 mg/dL or HbA1C <5.7
3.3 Willing to give informed consent
3.4 Number of adult family members less than 5

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
100 including diabetic (50 cases), Pre diabetic (25 cases) and Non diabetic (25 cases)

Total final enrolment
108

Key exclusion criteria
1. BMI more than or equal to 30 kg/m2
2. Patients consuming laxatives for more than twice a month
3. Consuming more than or equal to 20g alcohol per day and/or more than 10 cigarettes per day
4. Lactating or pregnant mothers
5. Regular users of rice bran oil, or sesame oil for the last 3 months
6. Those who take more than 2 major meals per week outside home or frequent travellers

Date of first enrolment
22/03/2018

Date of final enrolment

Locations

Countries of recruitment
India

Study participating centre
All India Institute of Medical Sciences, Bhubaneswar
Sijua
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Sponsor information

Organisation
Pharmainstinct

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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Other

Funder Name

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		11/02/2019	11/02/2019	No	Yes