

PARTICIPANT INFORMATION SHEET

Study Title: Effect of different cooking oils on blood sugar and cholesterol levels in persons with diabetes, without diabetes and likely to have diabetes

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Aim of the Study: The study will evaluate the effect of 12 week use of 20% sesame oil blended with Rice bran oil as a substituted cooking medium on changes in your blood cholesterol and sugar levels.

Objective: You will be evaluated for changes in blood glucose, insulin and cholesterol levels during 12 weeks of cooking oil use.

Procedure

Initially you will be investigated for eligibility for the research. Based on your blood glucose or HbA1C, you will be categorized as, **DIABETIC** (fasting blood Glucose greater than 125 mg/dL or HbA1C greater than 6.5), **PRE-DIABETIC** (fasting blood Glucose greater than 100 mg/dL and less than 125 mg/dL or HbA1C between 5.7 - 6.5) or **NON-DIABETIC** (fasting blood Glucose less than 100 mg/dL or HbA1c less than 5.7)

- If you are a stable **Diabetic on oral medicine**, you will be given either sesame oil blended with rice bran oil or soybean oil for cooking in a randomized manner. Your diabetes medicines will be continued as before and no change will be made.
- If you happen to be a **Non-Diabetic or a Pre-Diabetic individual**, you will be given sesame oil blended with rice bran oil for cooking

You will use one of these cooking oils for 12 weeks for the entire family. 5 mL of venous blood will be drawn at the start of the study and at 4 weeks intervals till 12th week of study for investigation.

Expected Benefit from the study: It has been known that the dietary cooking oil influences both cholesterol and glucose in the blood, but the effect varies from oil to oil and individual to individual. So far, there is limited information on the magnitude of this response following use of blended rice bran and sesame oil in Indian diabetes patients.

Any associated Risk from the study: Blended rice bran oil with sesame oil and soybean oil are approved by the Food Safety and Standards Authority of India (FSSAI), a government of India organization under the ministry of Health and family welfare and are available in the market and used by consumers regularly. Their safety and quality have been tested and approved and the health related risk is negligible.

Confidentiality: The study will be conducted in AIIMS Bhubaneswar only after the due approval of the Institute Ethics Committee. All the study related documents will be kept confidential which can only be accessed by authorized personnel.

You will not pay anything for participating in the study. The cooking oil that will be used in the study will be given for the entire family free of cost. Your participation in this study is purely voluntary and no penalty will be levied in case you opt out of the study. You can opt out of the study at any time without assigning any reason thereof. The contact details of the principal investigator is provided at the top and you may ask questions to him.
