Title:

Effect of Pomegranate Seed Powder on

markers of Metabolic Syndrome

NCT:

Not Assigned yet

Submission Date:

Uploaded here on 21st June, 2023

STATEMENT OF PROBLEM

A number of chronic disorders can lead to metabolic syndrome, which has been identified as one of the key risk factors for the epidemic of type 2 diabetes and cardiovascular diseases in the twenty-first century. Thus, it's a high time to mitigate the prevalence of these risk factors to overcome metabolic syndrome.

Objective:

To evaluate the effectiveness of pomegranate seed powder supplementation in preventing metabolic dysfunction and its main risk factors, such as hypertension and cardiovascular illnesses.

Study Protocol

Type of Study

This trail is prospective clinical type.

Supplement preparation

Pomegranate seeds and arils will be separated, and then the seeds will be dried for 15 days in a lab environment. Later, a mechanical grinder will be used to powder the dried seeds. PS powder (PSP) will be packed in a capsule form, 5 g in each.

Participants

The population under study will be consisted of people suffering with any of the three metabolic impairments; Insulin resistance, obesity, disturbed glucose level, hyper-cholesterol, hypertension and higher blood pressure. Exclusion criteria will be critically ill or hospitalized patients and individuals with digestion and absorption issues.

Span of study

The clinical trial on the 50 patients of metabolic syndrome will be conducted for the duration of 8 weeks with the supplementation of PSP capsule, twice a day.

Outcome Evaluation

Blood pressure, total cholesterol, and triglycerides (TG) will be measured at the enrollment point (i.e., baseline) and at the end of the 8-week intervention period. Fasting blood glucose (FBG), glycated haemoglobin (HbA1c), and triglycerides (TG) will be measured at the enrollment point (i.e., baseline). A fresh blood sample from a vein will then be taken and examined. A calibrated digital weight scale will also be used to check the patient's weight. Detail of all data collected is as follows:

Anthropometric Measurements:

- Weight
- Height
- Skin fold Thickness

Biochemical Evaluation:

- Blood Pressure
- Fasting Blood Glucose
- Total Cholesterol
- Triglycerides

Clinical Evaluation:

- Obesity

Statistical Analysis Plan

Using one-way ANOVA, the statistical significance of the host parameter data will be determined (SPSS Inc., Chicago, IL, USA). When the p-values are less than 0.05, differences are considered significant. Statistical analyses will be carried out in the R programming environment for data sequencing. For both quantitative and qualitative variables, data will be displayed as means ± SD or frequency (percent), respectively.