

3. STUDY PROTOCOL

AIMS & OBJECTIVE

1. Comparison of safety and efficacy of Statin (Rosuvastatin, Atorvastatin) verses Salveo Andaman Noni.
2. Comparison of efficacy of Rosuvastatin versus Atorvastatin (doses as prescribed by the physician) in patients with coronary heart disease or multiple risk factors for coronary heart disease.

DESIGN

Open labelled, non-randomized Comparative study of Efficacy and Safety statins (Rosuvastatin, Atorvastatin) verses Salveo Andaman Noni will be carried out in a tertiary care setting in kolkata, 2012.

Open-label: - A clinical trial in which doctors and participants know which drug is being administered. *Non-Randomized:-* Non-randomization is a process in which patients or subjects taking drug accordingly to treatment regiment. Comparison study means compare of the study drugs in the study. Efficacy defined as the maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trails if it is effective at dose tested and against the illness for which it is prescribed. In this procedure mandated by the FDA, Phase ii clinical trails gauge efficacy, and phase iii trails confirm it.

STUDY DURATION: Total Study Duration: 3 months

Phases of Treatment:

- Visit 1: Screening Phase: Patients are to be screened according to the inclusion and exclusion criteria. Week-1.
- Treatment Phase: 12 Weeks.
- Visit 2: 6 weeks after starting treatment.
- Visit 3: 12 weeks after starting treatment.
- End of Study.

STUDY TREATMENT: There will be five subgroups:

Treatment 1: Rosuvastatin tablet (10mg), OD

Treatment 2: Rosuvastatin tablet (20mg), OD

Treatment 3: Atorvastatin tablet (10mg), OD

Treatment 4: Atorvastatin tablet (20mg), OD

Treatment 5: Salveo Andaman Noni freeze dried powder (3.5 gm), BD

SETTING

Medica Super Specialty Hospital, a tertiary care setup in Kolkata.

Medica Superspecialty Hospital, a unit of Medica Synergic Pvt. Ltd. and one of the largest integrated healthcare delivery providers in eastern India, brings you the finest ambience and services for inpatient and outpatient treatment.

INCLUSION CRITERIA

Atorvastatin

*Adult patients without clinically evident CHD, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension and low HDL-C or family history of early coronary heart disease.

*Patients without clinically evident coronary heart disease, but with multiple risk factors for CHD such as retinopathy, albuminuria, smoking or hypertension.

*Patients with clinically evident CHD

Rosuvastatin

- Patients with elevated Total -C, LDL-C, Apo B, Patients with hyperlipidaemia or mixed dyslipidaemia.
- Patients with hyperlipidaemia or mixed dyslipidaemia.
- Patients with hypercholesterolemia

