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An open-label, prospective, non-comparative clinical trial to evaluate the efficacy and safety of rosuvastatin in high risk Indian population with diabetes and dyslipidemia

Submission date
04/09/2007

Recruitment status
No longer recruiting

Registration date
06/11/2007

Overall study status
Completed

Last Edited
06/11/2007

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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CT/RNBX CV-LIFE/07

Study information

Scientific Title

Acronym
RESIDD

Study objectives
Rosuvastatin is effective in treating high risk Indian population of diabetic patients who have abnormal lipid levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Dhanvantry Independent Ethics Committee on the 11th June 2007 (ref: RANB11/06/2007).

Study design
Open label, prospective, non-comparative clinical trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes patients with dyslipidemia

Interventions
Once the enrolment of the patient is through he will be kept on:
1. Tab. rosuvastatin 10 mg once a day if his LDL level ranges between 100 mg/dL to 130 mg/dL for first 6 weeks, or
2. Tab. rosuvastatin 20 mg once a day if his LDL level is above 130 mg/dL for first 6 weeks

Week 6 (first follow-up):
The patients lipid profile will be evaluated and if the patients LDL does not come under 100 mg

/dL as per the guidelines of National Cholesterol Education Program (NCEP)-Adult Treatment Panel (ATP) III then the dose will be doubled, i.e., patients on rosuvastatin 10 mg will receive rosuvastatin 20 mg and patients getting rosuvastatin 20 mg will be given rosuvastatin 40 mg. It will remain once a day therapy.

Week 12 (second and last follow-up - end of study):
Patients blood will be evaluated for the endpoints and the continuation of therapy will be on the treating clinician.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Rosuvastatin

Primary outcome measure
1. Mean change in total cholesterol
2. Mean change in LDL cholesterol
3. Mean change in High Density Lipoprotein (HDL) cholesterol
4. Mean change in triglycerides
5. Number of patients achieving ATP III target LDL of less than 100 mg/dl

Primary and secondary time points will be measured by evaluating the blood parameters on week 6 and week 12 against the baseline collected at the time of enrolment.

Secondary outcome measures
1. Mean change in the level of hs-CRP
2. Mean change in level of apoprotein B
3. Mean change in apoB/apoA1 ratio
4. Mean change in apoprotein A1
5. Mean change in lipoprotein a
6. Change in glycosylated haemoglobin at the end of study period
7. Incidence of hepatic dysfunction defined by liver enzyme elevation more than three times in the absence of other systemic cause
8. Compliance and side effects
9. Mean change in the level of creatinine kinase

Primary and secondary time points will be measured by evaluating the blood parameters on week 6 and week 12 against the baseline collected at the time of enrolment.

Overall study start date
15/09/2007

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Diabetes type II defined by American Diabetes Association criteria of fasting venous plasma glucose of greater than or equal to 126 mg/dl, two-hour post prandial plasma glucose of greater than or equal to 200 mg/dl or already on treatment of diabetes
2. Dyslipidemia defined by Low Density Lipoprotein (LDL) cholesterol more than 100 mg/dl or on prior statin therapy
3. Age of greater than or equal to 30 and less than or equal to 70 years
4. Informed consent by the patient

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
360

Key exclusion criteria
1. Failure to give informed consent
2. A history of hypersensitivity to statins
3. Evidence of fundoscopy grade 2 hypertensive or diabetic retinopathy
4. Serum creatinine greater than 1.5 mg/dl
5. Overt proteinuria
6. Pregnant or lactating mothers
7. Evidence/history of heart failure
8. Systolic blood pressure above 180 mmHg and diastolic blood pressure above 110 mmHg
9. Recent history of cerebrovascular disease, myocardial infarction, unstable angina, new onset Left Bundle Branch Block (LBBB) in the past 4 weeks
10. Documented case of homozygous familial hypercholesterolemia
11. Type I Diabetes Mellitus (DM)
12. Use of concomitant medications (cyclosporin, systemic itraconazole or ketoconazole, erythromycin, or clarithromycin, glucocorticoids or verapamil) known to affect the lipid profile or with potency safety concern
13. Recent ongoing inter-current infection/high sensitivity C-Reactive Protein (hsCRP) greater than 10 mg/L
14. Active liver disease or hepatic dysfunction (defined as Alanine aminotransferase [ALT], aspartate aminotransferase [AST], Gamma-Glutamyl Transferase [GGT], alkaline phosphate or bilirubin levels greater than or equal to 1.5 the upper limit of normal)
15. Diagnosed to have any other endocrinal or metabolic disease other than Type II DM that is known to influence serum lipids and lipoproteins
16. Patients having history suggestive of myalgia/myositis/arthralgia
17. Serious or unstable medical or psychological condition that could compromise the patients safety or successful trial participation
18. History of alcohol consumption greater than 2 drinks/day (30 ml) or 10 drinks per week

Date of first enrolment
15/09/2007

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
India

Study participating centre
Ranbaxy Laboratories Ltd
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Sponsor information

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Funder(s)

Funder type
Industry

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Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration