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Study on the safety and efficacy of sylvan Red Yeast Rice in adults with primary hypercholesteremia

Submission date	Recruitment status	[ ] Prospectively registered
02/06/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/10/2009	Nutritional, Metabolic, Endocrine	[ ] 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

Protocol serial number
CTN RR 141

Study information

Scientific Title

Acronym
RYR

Study objectives
Treatment with Red Yeast Rice will significantly lower Low-Density Lipoprotein (LDL) levels.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypercholesteremia

Interventions
Red Yeast Rice Stage One: This stage is a randomised, double blind, placebo-controlled, three arm parallel study. The study will compare baseline lipid levels with post-treatment levels for the treatment and placebo groups over a 12-week period. Interim analyses of the data will be conducted at the completion of stage one, and subjects will be issued with the active medication at the end of week 12. The analysis of data will continue for eight weeks.
16 weeks - Four weeks wash out for subjects ceasing lipid-lowering agents. After determination of baseline lipid levels subjects will be assigned to 12 weeks of treatment.
Interim analysis of data eight weeks. Subjects will continue on active treatment.
Arm one: 24 participants taking two active capsules, with a meal in the morning and two placebo capsules with a meal at night
Arm two: 24 participants taking two active capsules with a meal in the morning and two active capsules with a meal at night
Arm three: 24 participants taking two placebo capsules with a meal in the morning and two placebo capsules with a meal at night

Stage Two: An open labelled study where all subjects receive the active treatment over 32 weeks. Participants taking two active capsules with a meal in the morning and two active capsules with a meal at night.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Red Yeast Rice

Primary outcome(s)
Change in LDL cholesterol from baseline to end of treatment.

Key secondary outcome(s)
Change in total cholesterol, High-Density Lipoprotein cholesterol (HDL) and triglycerides.

Completion date
30/07/2005

Eligibility

Key inclusion criteria
1. LDL cholesterol more than or equal to 3.5 to less than or equal to 5.7 mmol/l
2. Aged 18 to 75 years
3. Body mass index less than or equal to 32 kg/m^2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Triglyceride levels more than 4 mmol/l
2. Total cholesterol more than 10 mmol/l
3. Use of lipid lowering medications including herbal and other "natural" lipid lowering agents within one month of baseline
4. Liver function enzymes more than three times the upper limit of normal at baseline
5. Pregnant women or women unwilling to use birth control for the duration of the study
6. Diabetes
7. Hypothyroidism
8. Smoking
9. Cardiovascular disease
10. Subjects unwilling to comply with study protocol
11. Poor venous access
12. Any other condition, which in the opinion of the investigators could compromise the study

Date of first enrolment
01/07/2005

Date of final enrolment
30/07/2005

Locations

Countries of recruitment
Australia

Study participating centre
P.O. Box 157
Lismore
Australia
2480

Sponsor information

Organisation
Sylvan Health Pty Ltd (Australia)

Funder(s)

Funder type
Industry

Funder Name
Sylvan Health Pty Ltd (Australia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration