A Randomised, Double-Blind, Placebo-Controlled, Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and the Effect of Food on the Pharmacokinetics of DRL-17822 in Healthy Adult Male Volunteers

Published: 20-03-2009
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Part I (single ascending dose):To evaluate the safety and tolerability of ascending single doses of DRL-17822 in healthy male subjects;To evaluate the pharmacokinetics of ascending single doses of DRL-17822 in healthy male subjects;To determine CETP...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON33454

Source
ToetsingOnline

Brief title
Study protocol DRL-17822/CD/001

Condition

- Coronary artery disorders

Synonym
Atherosclerosis, coronary heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Dr. Reddy's Laboratories Ltd.
Source(s) of monetary or material Support: Dr. Reddy's Laboratories Ltd.

Intervention

Keyword: Cardiovascular disease, Food effect, Multiple dose, Single dose

Outcome measures

Primary outcome

Part I (single ascending dose):

To evaluate the safety and tolerability of ascending single doses of DRL-17822

in healthy male subjects.

Part II (food effect evaluation):

To evaluate the effect of food on the pharmacokinetics of a single dose of

DRL-17822 in healthy male subjects.

Part III (multiple ascending dose):

To evaluate the safety and tolerability of ascending multiple doses of

DRL-17822 in healthy male subjects.

Secondary outcome

Part I (single ascending dose):

To evaluate the pharmacokinetics of ascending single doses of DRL-17822 in

healthy male subjects;

To determine CETP activity in the plasma of healthy male subjects following

ascending single doses of DRL-17822.

2Part II (food effect evaluation):

To evaluate the safety of a single dose of DRL-17822 in healthy male subjects;

To determine CETP activity in the plasma of healthy male subjects following a

single dose of DRL-17822.

Part III (multiple ascending dose):

To evaluate the pharmacokinetics of ascending multiple doses of DRL-17822 in

healthy male subjects with HDL-C levels <= 1.3 mmol/L;

To determine the steady state levels of ascending multiple doses of DRL-17822

in healthy male subjects with HDL-C levels <= 1.3 mmol/L;

To evaluate the pharmacodynamic effect(s) of ascending multiple doses of

DRL-17822 in healthy male subjects with HDL-C levels <= 1.3 mmol/L.

Study description

Background summary

DRL-17822 is a new investigational drug developed to inhibit the enzyme CETP (cholesterol ester transfer protein). CETP plays an important role with the metabolism of HDL cholesterol (good cholesterol) to LDL cholesterol (bad cholesterol). Studies showed that a high HDL cholesterol level and low level LDL cholesterol gives less riscs on cardiovascular disorders. By inhibiting CETP, the amount of HDL cholesterol will rise compared to LDL cholesterol. This could protect against cardiovascular disorders.

Study objective

Part I (single ascending dose):
To evaluate the safety and tolerability of ascending single doses of DRL-17822 in healthy male subjects;
To evaluate the pharmacokinetics of ascending single doses of DRL-17822 in healthy male subjects;
To determine CETP activity in the plasma of healthy male subjects following ascending single doses of DRL-17822.

2Part II (food effect evaluation):
To evaluate the effect of food on the pharmacokinetics of a single dose of DRL-17822 in healthy male subjects;
To evaluate the safety of a single dose of DRL-17822 in healthy male subjects;
To determine CETP activity in the plasma of healthy male subjects following a single dose of DRL-17822.

Part III (multiple ascending dose):
To evaluate the safety and tolerability of ascending multiple doses of DRL-17822 in healthy male subjects with HDL-C levels <= 1.3 mmol/L;
To evaluate the pharmacokinetics of ascending multiple doses of DRL-17822 in healthy male subjects with HDL-C levels <= 1.3 mmol/L;
To determine the steady state levels of ascending multiple doses of DRL-17822 in healthy male subjects with HDL-C levels <= 1.3 mmol/L;
To evaluate the pharmacodynamic effect(s) of ascending multiple doses of DRL-17822 in healthy male subjects with HDL-C levels <= 1.3 mmol/L.

Study design

Randomised, double-blind, placebo-controlled study.

Intervention

The volunteers will participate in two sessions. In the one session, the investigational drug will be administered in a fasted state, in the other session the investigational drug will be administered after a breakfast.

Study burden and risks

The risks associated with this investigation are linked together with the possible side effects of the investigational product. The burden on the volunteer will continue to work with the recording periods, assessments performed during the trial, venapunctions and the introduction of the cannula. All volunteers are closely monitored and supervised by experienced doctors and studystaff for possible side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Male subjects, 18-45 years of age, inclusive (Parts I and II), 18-55 years of age, inclusive (Part III);
2.Body mass index (BMI) >= 18.0 and <= 28.0 kg/m2 (Parts I and II), >= 18.0 and <= 30.0 kg/m2 (Part III);
3. HDL-C levels <= 1.3 mmol/L at Screening (Part III only);
4. Informed consent;
5. Good health, based upon the results of the screening;
6.Venous access sufficient to allow blood sampling as per protocol;

Exclusion criteria

1. Positive for hepatitis B, C or HIV;
2. Positive drug screen result at Screening or on Day -1;
3. Positive alcohol breath test result at Screening or during admission;
4. Use of prescription medication within 2 weeks prior to Day 1;
5. Use of over-the-counter medication (including homeopathic medicines) within 4 days prior to Day 1, excluding routine vitamins and incidental use of paracetamol;
6. History of clinically significant haematologic, renal, hepatic, cardiovascular, neurologic, endocrinal, oncologic, pulmonary, immunologic, or psychiatric disorders;
7. History of clinically significant allergies;
8. Unwilling to comply with contraceptive measures up to 90 days after last dosing;
9. Presence or history of alcoholism or drug abuse;
10. Use of more than 21 units of alcohol per week;
11. Smoking ;
12. Participation in an investigational drug study within 90 days prior to Day 1;
13. Loss or donation of >350 mL of blood within 90 days prior to Day 1;
14. Unsuitable to participate in the study for any reason in the opinion of the PI.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2009
Enrollment:	72
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	DRL-17822
Generic name:	DRL-17822

Ethics review

Approved WMO Date:	20-03-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-04-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-06-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-06-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-10-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	05-10-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2009-010835-41-NL
CCMO	NL27152.040.09