A Phase I randomised, double-blind, 2-way cross-over study to compare the peripheral vasodilatation following treatment with DRL 21994 or NIASPAN® and to determine the pharmacokinetics of DRL 21994 in healthy, adult male subjects under fed conditions.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Lipid metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON33352

Source
ToetsingOnline

Brief title
Study Protocol DRL21994/CD/001

Condition

- Lipid metabolism disorders

Synonym
high blood fat, hyperlipidaemia

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: DRL-21994, Niaspan, pharmacokinetics, vasodilatation

Outcome measures

Primary outcome

The impact of DRL-21994 and Niaspin on the release of blood vessels.

Secondary outcome

The speed with which DRL-21994 is included in the body and the degree of

degradation and excretion of DRL-21994 and its degradation products. Also,

The safety and tolerability of DRL-21994 after a single dose of DRL-21994 .

Study description

Background summary

In this study, the DRL-21994 is compared with a registered agent (Niaspan). The two funds are different preparation forms of nicotinic acid (vitamin B7).

An abnormal fat in the blood, particularly cholesterol and triglycerides may contribute to the development of cardiovascular disease. Cholesterol is divided into "good" cholesterol (HDL-cholesterol) and "bad" cholesterol (LDL-cholesterol).
Niaspan has a beneficial effect on fat in the blood. It increases the amount of HDL cholesterol and lowers the quantities of LDL-cholesterol and triglycerides.

Niaspan is used to a different fat content in the blood, especially at elevated LDL-cholesterol and triglycerides and reduced HDL-cholesterol (dyslipidemie)

and increased cholesterol in the blood (hypercholesterolemie).

Study objective

The aim of the study is twofold.
The first is the impact of DRL-21994 and the registered product on the release of vessels studied and compared.
The second is the speed with which DRL-21994 is included in the body examined, as well as the degree of degradation and excretion of DRL-21994 and its degradation products. Also, the safety and tolerability of DRL-21994 after a single dose of DRL-21994.

Study design

One group of 18 healthy male volunteers will participate in this research. The examination includes a medical examination, 2 admissionperiods of four days and finally a retesting.

Intervention

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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, 18-55 years of age at Screening, extremes included;
2. Body mass index (BMI) >= 18 and <= 30 kg/m2;
3. Venous access sufficient to allow blood sampling as per protocol;
4. Ability and willingness to give written informed consent;
5. Good health, based upon the results of medical history, physical examination, vital signs, ECG, and laboratory profiles of both blood and urine.

Exclusion criteria

1. Positive for hepatitis B, C or HIV;
2. Positive drug screen result (i.e. cocaine, opiates, amphetamine, cannabis, barbiturates, benzodiazepines, and/or methadone);
3. Positive alcohol breath test result;
4. Use of prescription medication within 4 weeks prior to Day 1;
5. Use of over-the-counter medication (including homeopathic medicines) within 2 weeks prior to Day 1, including routine vitamins. Regular use of non-drug therapies such as garlic supplementation and St John*s Wort;
6. Use of non steroidal anti inflammatory agents (e.g. aspirin, ibuprofen) within 2 weeks of treatment;
7. Presence or history of alcoholism or drug abuse;
8. History or diagnosis of clinically significant haematological, hepatic, renal, cardiovascular, neurological, endocrinological, oncological, psychiatric or any other major medical illness;
9. Use of more than 21 units of alcohol per week;

10. Smoking (subjects have to be non-smokers for at least 3 months preceding Screening);
11. History of clinically significant allergies, including relevant drug hypersensitivity or allergy;
12. Administration of an investigational drug within 90 days prior to Day 1;
13. Loss or donation of >350 mL of blood within 12 weeks 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
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-07-2009
Enrollment:	18
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	DRL-21994
Generic name:	DRL-21994
Product type:	Medicine
Brand name:	Niaspan
Generic name:	Niacin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-04-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-04-2009
Application type:	First submission
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	EUCTR2009-011376-29-NL
CCMO	NL27478.040.09