A placebo-controlled, double-blind, randomised, multiple dose, dose escalating study in healthy subjects to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of SPC3649

Published: 28-05-2009
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Main objective• To determine the safety and tolerability of multiple dosing of SPC3649Secondary objectives• To assess the pharmacokinetics (PK) of multiple dosing of SPC3649 administered by i.v. and s.c. route in healthy volunteers• To evaluate the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON33484

Source
ToetsingOnline

Brief title
SPC3649 multiple dose study in healthy volunteers

Condition

- Viral infectious disorders

Synonym
Hepatitis C, liver inflammation

Research involving

Human

Sponsors and support

Primary sponsor: Santaris Pharma A/S
Source(s) of monetary or material Support: Sponsor: Santaris Pharma A/S

Intervention

Keyword: Healthy volunteers, multiple dose, oligonucleotide antisense, SPC3649

Outcome measures

Primary outcome

To determine the safety and tolerability of multiple dosing of SPC3649

Secondary outcome

• To assess the pharmacokinetics (PK) of multiple dosing of SPC3649

administered by i.v. and s.c. route in healthy volunteers

• To evaluate the bioavailability of s.c. administration of SPC3649

• To investigate the effect of multiple dosing of SPC3649 on lipids as

surrogate markers of miR-122 inhibition

Study description

Background summary

Possible new treatment of Hepatitis C with SPC3649

Study objective

Main objective
• To determine the safety and tolerability of multiple dosing of SPC3649

Secondary objectives
• To assess the pharmacokinetics (PK) of multiple dosing of SPC3649
administered by i.v. and s.c. route in healthy volunteers
• To evaluate the bioavailability of s.c. administration of SPC3649

• To investigate the effect of multiple dosing of SPC3649 on lipids as surrogate markers

Study design

This is a placebo-controlled, double-blind, randomised, multiple dose-escalating safety study in healthy volunteers, each subject will receive 5 doses either as a 2 hour intravenous infusion (i.v.) or as a subcutaneous (s.c.) injection with either SPC3649 or placebo once weekly.

Intervention

Treatment with SPC3649

Study burden and risks

The total study duration is 6 month and during that time the subjects will be admitted to the clinic for 2 x 24 hours and they will visit the clinic on regular ambulatory visits. The medication will be administered as i.v. or s.c. injections. During each visit blood samples will be drawn. Blood sampling can give light pain and very seldom infection. In the first study 48 subjects were treated with a single dose of SPC3649 as i.v. infusion without any injection site reaction. However, s.c. injection could cause mild and temporal injection site reaction as known from other antisense drugs. . In the First-in-Man study overall SPC3649 appeared to be safe and well tolerated. The adverse events observed were mild or moderate and resolved spontaneously. In this study the lipids were reduced, which can also be expected in this study. It is not expected that the study subjects will have any lasting benefits from participation in the study.

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

• Healthy volunteers
• Males, postmenopausal (>1 year since last menstruation) or hysterectomised female
• Age >=18 to 60 years
• BMI: 18 - 30 kg/m2
• No clinically significant disease/disorder
• No clinically significant abnormalities at Screening laboratory tests
• Male subjects must agree to use birth control (condoms) during the whole study period
• Following receipt of verbal and written information about the study, the subject must provide signed informed consent before any study related activity is carried out

Exclusion criteria

• Alcohol intake >=21 units weekly for men, and >=14 units for women
• smoke >10 cigarettes per day
• Received experimental drug within 60 days of study entry
• Planned participation in any experimental study during the study period
• HIV-Ab, HBsAg and/or HCV Ab positive
• Abnormal blood pressure (systolic >140 mmHg and/or diastolic blood pressure >90 mmHg)
• Current use of any drug or narcotics

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2009
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	SPC3649
Generic name:	SPC3649

Ethics review

Approved WMO Date:	28-05-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-07-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-09-2010
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	EUCTR2009-012153-38-NL
CCMO	NL28003.000.09