A randomized, double-blind placebo- and active-controlled study of the pharmacokinetics, pharmacodynamics and safety of single ascending doses of HM10660A (LAPS-Interferon Alpha-2B) in healthy male subjects

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to study the safety and tolerability of HM10660A (LAPS-interferon alpha-2b), including immunogenicity, as compared to Pegasys® (PEG-interferon alpha-2a)to study the pharmacokinetics and pharmacodynamics of HM10660A (LAPS interferon alpha-2b) as...

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

Summary

ID

NL-OMON35906

Source
ToetsingOnline

Brief title
HM10660A first-in-man study

Condition

- Viral infectious disorders
- Miscellaneous and site unspecified neoplasms benign

Synonym
C, Hepatitis B, viral liver inflamation

Research involving
Human

Sponsors and support

Primary sponsor: Hanmi Pharmaceutical Company Limited
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: Hepatitis, HM10660A, pharmacokinetics, safety

Outcome measures

Primary outcome

safety and tolerability

Secondary outcome

pharmacokinetics

pharmacodynamics

Study description

Background summary

The drug to be given HM10660A is a new, investigational compound that may eventually be used for the treatment of hepatitis B, C (viral infections of the liver) and cancer. Human interferon alfa-2b (IFN*2b) is a protein that modifies the response of the body's immune system to help fight infections and severe diseases. It is active against viral infections and the spreading of some types of cancer in the body. Recombinant human interferon alfa-2B is the same enzyme produced in bacteria that is used in the treatment of chronic Hepatitis B and C and some types of cancer. A disadvantage of recombinant human interferon alfa-2b is the need for frequent administration and the duration of the treatment (48 weeks). HM10660A is a recombinant human interferon alfa-2b linked to another human protein in development to make it long acting thus allowing weekly to monthly injections with a higher effect.
This new compound is not registered as a drug. This is the first time that this compound is being given to humans.
During the study you may be receiving HM10660A, Pegasys or placebo. Pegasys is a long-acting interferon that is registered for the use in the treatment of

chronic hepatitis B or C.

Study objective

to study the safety and tolerability of HM10660A (LAPS-interferon alpha-2b), including immunogenicity, as compared to Pegasys® (PEG-interferon alpha-2a)
to study the pharmacokinetics and pharmacodynamics of HM10660A (LAPS interferon alpha-2b) as compared to Pegasys® (PEG-interferon alpha-2a)

Study design

Design:
a randomized, double-blind, placebo- and active-controlled, single-dose study in 4 groups of 12 healthy male subjects each. In each group, 8 subjects will receive a single subcutaneous (sc) dose of HM10660A, 2 subjects will receive a single sc dose of placebo and 2 subjects will receive a single sc dose of Pegasys®.

Screening :
demographics, medical history, clinical laboratory, physical examination (including height and body weight), vital signs , 12-lead electrocardiogram (ECG), drug and alcohol screen, HBsAg, anti HCV and anti-HIV 1/2, blood sampling for anti-glutamic acid decarboxylase ((anti GAD) antibodies and for anti-thyroid peroxidase (anti-TPO) antibodies, Columbia Suicide Severity Rating Scale (C-SSRS), adverse events (AEs), previous and concomitant medication, and eligibility check
Admission :
clinical laboratory (including clinical chemistry, hematology and urinalysis), physical examination, vital signs (including supine systolic and diastolic blood pressure, pulse rate and oral body temperature), 12-lead ECG, drug and alcohol screen, AEs, previous and concomitant medication, and eligibility check
Follow-up (Day 43) :
clinical laboratory (including clinical chemistry, hematology and urinalysis), physical examination, vital signs (including supine systolic and diastolic blood pressure, pulse rate and oral body temperature), 12-lead ECG, C-SSRS, blood sampling for PK and immunogenicity, AEs and concomitant medication
Observation period :
- Groups 1 and 2: in clinic from the afternoon preceding drug administration up to 168 h (Day 8) after drug administration and ambulatory visits on Days 11, 15, 22 and 29
- Groups 3 and 4: in clinic from the afternoon preceding drug administration up to 240 h (Day 11) after drug administration and ambulatory visits on Days 15, 22 and 29
Blood sampling :
- for pharmacokinetics (PK) of HM10660A and Pegasys® in serum: at pre-dose and at 2, 6, 12, 24, 48, 72, 96, 120, 168, 240, 336, 504, 672 h and 1008 h post-dose

- for pharmacodynamics (PD; 2*-5*-OAS and neopterin in serum): at pre-dose and at 6, 12, 24, 48, 72, 96, 120, 168, 240, 336, 504 and 672 h post-dose
- for immunogenicity: at pre-dose and at 336, 504, 672 and 1008 h post-dose.

Safety assessments :
AEs: throughout the study period
clinical laboratory:
- clinical chemistry and hematology: at 12, 24, 48 and 72 h post-dose and once on Days 8, 15 and 29;
- urinalysis: at 6 h post-dose;

vital signs (including supine systolic and diastolic blood pressure, pulse rate and oral body temperature): at 1, 6, 12, 24, 48, 72 and 96 h post-dose and once on Days 8, 11, 15, 22 and 29;
body temperature only: once on Days 6 and 7

12-lead ECG: at 1, 6, 12, 24, 48, 72 and 96 h post-dose and once on Days 8 and 15;
physical examination (directed by symptoms): at 24, 48 and 96 h post-dose and once on Days 8 and 15;

local tolerability at injection site: at 3, 12, 24, 48 and 72 h post-dose;

C-SSRS: once on Days 8, 11, 15, 22 and 29

Bioanalysis :
- analysis of serum PK samples for HM10660A and Pegasys® by PRA using a validated method
- analysis of 2*-5*-OAS and neopterin in serum by PRA using a validated method
- analysis of immunogenicity in serum by PRA using a validated method

Intervention

Active substance: HM10660A, Pegasys (PEG interferon alfa) or placebo

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

Contacts

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Scientific
Hanmi Pharmaceutical Company Limited

45, Bangi-dong,
Seoul
KR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Gender: male
Age: 18 * 45 years, inclusive
BMI: 18.0 * 28.0 kg/m2, inclusive

Exclusion criteria

Suffering from: hepatitis B, C, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 60 days from the start of the study or in case of donating more than 1.5 liter of blood in the 10 months prior the start of this study.

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):	28-03-2011
Enrollment:	48
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Pegasys
Generic name:	PEG-interferon alpha-2a
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-03-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	22-03-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2011-000331-80-NL
CCMO	NL35892.056.11

Study results

Date completed:	04-12-2011
Actual enrolment:	48