Single centre, randomised, open-label, 2-dose, parallel trial to compare immunogenicity, safety, tolerability, and pharmacodynamics of MYL-1401H and US-licensed Pegfilgastrim (NEULASTA®) after two subcutaneous (SC) injections at one dose level (6 MG) in healthy subjects.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	White blood cell disorders
Study type	Interventional

Summary

ID

NL-OMON42699

Source
ToetsingOnline

Brief title
MYL-1401H Immunogenicity comparability trial to US-Neulasta®

Condition

- White blood cell disorders

Synonym
Neutropenia

Research involving
Human

Sponsors and support

Primary sponsor: Mylan GmbH
Source(s) of monetary or material Support: Farmaceutische industrie.

Intervention

Keyword: MYL-1401H, Neutropenia

Outcome measures

Primary outcome

Immunogenicity/safety/tolerability/pharmacodynamics; side effects, lab data,

vital signs, ECG and physical examination.

Secondary outcome

Immunogenicity: Serum ADA concentrations

Pharmacodynamics : Absolute neutrophil count (ANC) in periods 1 and 2: area

under the effective concentration-time curve (AUEC) and ANCmax and derived PD

parameters (AUEC0-t, Cmax and tmax)

Study description

Background summary

Neulasta® is a drug registered for treatment of a shortage of white blood cells in order to prevent infections. It is used mostly for cancer patients to treat the side effects of chemotherapy. Neulasta® is the brand name; the active ingredient is called pegfilgrastim. This is a protein which is very similar to the human version *granulocyte colony stimulating factor* (also known as GCSF or filgrastim). GCSF is present in the human body by nature. Therefore, Neulasta® is called a *biological*. The difference between naturally occurring

GCSF and Neulasta® (pegfilgrastim) is the attachment of a large chain of molecules (a polymer) to pegfilgrastim. This makes the protein stay longer in the body so patients need to receive drug less often to achieve the same effect. MYL-1401H is a new pegfilgrastim strongly resembling Neulasta®. Both Neulasta® and MYL-1401H are produced with the help of bacteria which have received a human gene which makes them able to produce this protein. MYL-1401H is not registered as a drug but has been given to humans before. In this study the volunteers will receive MYL-1401H or Neulasta® US (United States licensed product) on two separate occasions.

Study objective

The purpose of the study is to investigate the ability of MYL-1401H to evoke an immune response (immunogenicity) as compared to Neulasta® US. In addition, the effect of MYL-1401H on blood cells as compared to Neulasta® US will be investigated. The study further investigates how quickly and to what extent MYL-1401H is absorbed and eliminated from the body (this is called pharmacokinetics) as compared to Neulasta® US. Furthermore, it will be investigated to what extent MYL-1401H is tolerated.

For the purpose of the study the concentration of pegfilgrastim, the amounts of certain types of white blood cells and the possible development of antibodies against pegfilgrastim in the volunteers blood will be investigated.

Study design

The actual study will consist of 2 periods during which the volunteers will stay in the clinical research center in Zuidlaren for 4 days (3 nights). Each period is followed by 3 ambulant visits during which they will visit the clinical research center in Zuidlaren. The time interval between the different periods (time between two administrations of study compound) is 4 weeks.

In each period, Day 1 is the day of administration of study compound. The volunteers are expected at the clinical research center at 14:00 h in the afternoon prior to the day of administration of study compound. They will be required not to have consumed any food or drinks during the 4 hours prior to arrival in the clinical research center (with the exception of water).They will leave the clinical research center on Day 3 and the volunteers will return for the ambulant visits on Days 7, 15 and 22. For the ambulant visits they are expected at the clinical research center in Zuidlaren.

Intervention

Each period a dosage of 0.6 mL MYL-1401H or Neulasta® US by subcutane (SC) injection.

Study burden and risks

During the investigation, various assessements will be done that can be experienced as more or less stressfull.
Blood draw, SC injections and the ECG can be experienced as stressfull in this respect.

Contacts

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Scientific
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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 male or female subjects
18 - 65 years of age, inclusive
BMI 19.0 - 30.0 kilograms/meter2

weight at least 60.0 kilograms
non-smoking or smoke maximally 5 cigarettes per day

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	na
Generic name:	pegfilgrastim
Product type:	Medicine
Brand name:	US NEULASTA®
Generic name:	US NEULASTA®

Ethics review

Approved WMO Date:	29-07-2015
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	EUCTR2015-002599-26-NL
CCMO	NL54210.056.15