Single center, randomized, double-blind, 3-period, 3 treatments, 3 way crossover pharmacokinetics (PK)/pharmacodynamics (PD) trial to assess PK, PD, safety and tolerability of MYL-1401H after single subcutaneous injection at one dose level (2 mg) comparing to an EU and US marketed drug product (NEULASTA®) in healthy volunteers.

Published: 14-07-2014
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The purpose of the study is to investigate how quickly and to what extent MYL-1401H is absorbed and eliminated from the body (this is called pharmacokinetics) as compared to Neulasta® EU and US. It will also be investigated what the effect is of MYL...

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

Summary

ID

NL-OMON40799

Source
ToetsingOnline

Brief title
MYL-1401H bio-equivalency study to EU- and US marketed 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

Pharmacokinetics/Pharmacodynamics and safety; adverse events, laboratory data,

vital signs, ECG and physical examination.

Secondary outcome

PD: general linear model (GLM) analyses of variance (ANOVA) on ANC AUC0-t, ANC

Cmax, and ANC tmax and on CD34+ AUC0-t, CD34+ Cmax and CD34+ tmax; descriptive

statistics

PK: GLM ANOVA on AUC0-inf, Cmax, AUC0-t, tmax, kel, t1/2 and Vd/F; descriptive

statistics

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 pegfilgrastim is the attachment of a large chain of molecules (a polymer) to the protein. 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. This is the first time that the MYL-1401H compound is being given to humans.

In this study the volunteers will receive MYL-1401H, Neulasta® EU (EU-licensed product) and Neulasta® US (US licensed product) on three separate occasions.

Study objective

The purpose of the study is to investigate how quickly and to what extent MYL-1401H is absorbed and eliminated from the body (this is called pharmacokinetics) as compared to Neulasta® EU and US. It will also be investigated what the effect is of MYL-1401H on blood cells as compared to the two Neulasta® versions. Finally, it will be investigated to what extent MYL-1401H is tolerated.

Study design

This study is a single center, randomized, double-blind, 3-period, 3 treatments, 3 way crossover pharmacokinetics (PK)/pharmacodynamics (PD) trial to assess PK, PD, safety and tolerability of MYL-1401H after single subcutaneous injection at one dose level (2 mg) comparing to an EU and US marketed drug product (NEULASTA®) in healthy volunteers.

The actual study will consist of 3 periods. In each period the volunteer will stay in the clinical research center in Groningen for 7 days (6 nights) followed by a period of 17 days during which they will visit the clinical research center in Groningen on 7 occasions (on Day 6, Day 7, Day 8, Day 9, Day 12, Day 15 and Day 22 of each period). After the 3rd and last period, the post-study screening will take place on Day 29. The duration of the different periods is at least 4 weeks.

At the beginning of each period (Day 1) the volunteer will receive MYL-1401H, Neulasta® EU or Neulasta® US after breakfast in the morning. They will receive one injection of 0.2 mL under the skin of the abdomen. After drug administration they will be required to remain in a lying position for at least

4 hours. During this period, lying on the stomach is not allowed.

Intervention

Repeated single dose of 2 mg study drug delivered by 0.2 ml subcutaneous (SC) injections.

Study burden and risks

During the investigation, various assessments 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

Public
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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 kg
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:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2014
Enrollment:	216
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	EU Neulasta®
Generic name:	EU Neulasta®
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	US Neulasta®
Generic name:	US Neulasta®

Ethics review

Approved WMO Date:	14-07-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-07-2014
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	EUCTR2014-002229-37-NL
CCMO	NL49947.056.14