A phase I double-blind, placebo-controlled, safety, tolerability, pharmacokinetic and pharmacodynamic study of ascending single doses of ANF-Rho in comparison to standard of care-Neulasta® in healthy volunteers

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The purpose of the study is research. The study investigates to what extent ANF Rho is tolerated in comparison to Neulasta® (representing standard of care treatment) and placebo. A placebo is the same formulation as the study medication without the...

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

Summary

ID

NL-OMON41975

Source
ToetsingOnline

Brief title
ANF-Rho Phase I study in HV and comparability with Neulasta

Condition

- White blood cell disorders

Synonym
shortage of white blood cells

Research involving

Human

Sponsors and support

Primary sponsor: Prolong Pharmaceuticals, LLC
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: ANF-Rho, biological, Neulasta®

Outcome measures

Primary outcome

To determine the plasma pharmacokinetic profiles of ANF-Rho at ascending single dose in healthy volunteers in comparison to Neulasta® (SOC).

Secondary outcome

Pharmacodynamic:

-To determine the effect on absolute neutrophil counts (ANC) and CD 34+ cells in increasing doses of ANF-Rho in healthy volunteers in comparison to placebo and Neulasta®.

To assess the immunogenicity potential of ANF-Rho by measuring antibodies and neutralizing antibodies to ANF-Rho following a single subcutaneous dose.

To assess the occurrence and severity on bone pain in increasing doses of ANF-Rho in healthy volunteers in comparison to placebo and Neulasta®.

Study description

Background summary

ANF Rho is a new kind of pegfilgrastim which is similar to Neulasta®. 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 of the growth factor *granulocyte colony stimulating factor* (also known as G-CSF or filgrastim). G-CSF is present in the human body by nature. Therefore, Neulasta® is called a *biological*. The difference between naturally occurring G-CSF 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. ANF Rho is similar to Neulasta® but contains somewhat more polymer. Both Neulasta® and ANF Rho 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 ANF Rho compound is being given to humans.

Study objective

The purpose of the study is research.

The study investigates to what extent ANF Rho is tolerated in comparison to Neulasta® (representing standard of care treatment) and placebo. A placebo is the same formulation as the study medication without the active ingredient. It will also be investigated how quickly and to what extent ANF Rho is absorbed and eliminated from the body (this is called pharmacokinetics). In addition, the effect of the compound on blood cells and bone will be investigated (this is called pharmacodynamics).

This study will be performed in maximally 93 male and/or female volunteers divided over 9 groups of 5 to 12 participants each.

Study design

The actual study will consist of 1 period during which you will stay in the clinical research center in Zuidlaren for 8 days (7 nights) followed by 14 days during which you will visit the clinical research center in Zuidlaren on 4 occasions (on Day 8, Day 10, Day 12, Day 14). The follow-up visit will take place on Day 22. Your participation to the entire study, from pre-study screening until the post study screening, will be maximally 7 weeks.

Intervention

On Day 1 you will receive ANF Rho, Neulasta® or placebo after breakfast in the morning through an injection under the skin of the abdomen. In the highest dose group (50 µg/kg) of ANF Rho, the dose will be split into 2 subcutaneous

injections. The injection volume will be less than 1 mL per injection.

Study burden and risks

All potential drugs cause side effects; the extent to which this occurs differs. The overall risks of ANF Rho administration are considered to be minimal, although some are unforeseeable as the testing of this drug is still at an early stage. As ANF Rho will be administered to humans in this study for the first time, side effects in humans have not been reported to date. With the dose used in this study no serious side effects are expected, but as all drugs may potentially cause side effects to some extent, the occurrence of known or other effects cannot be excluded. This means that there is a chance of a minor side effect and a remote chance of something serious happening. It is expected that ANF Rho, which resembles Neulasta®, will likely have the same side effects as Neulasta®.

Neulasta® has been used now for 12 years and has been registered as a drug in over 100 countries worldwide. The most common side effects of Neulasta® (seen in more than 1 in 10 patients) are bone and muscle pain, headache and nausea (feeling sick). Other common side effects (seen in between 1 in 10 and 1 in 100 patients) are reactions where the injection is given such as pain. Less common but potentially serious reactions can include a low number of blood platelets, allergic reactions, rapid drop in blood pressure, enlarged or ruptured spleen, skin reactions and lung problems.

The body may recognize ANF Rho as foreign. As a result an immune response can occur, for example by making antibodies against the study medication. However, based on experience with Neulasta®, the chance of this happening is considered very low.

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 male/female subjects
18-55 yrs, inclusive
BMI: 18.0-30.0 kg/m2, inclusive

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 12 weeks from the start of the study. In case of donating more than 1.5 liters of blood (for men) or 1.0 liter of blood (for women) 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):	12-09-2014
Enrollment:	83
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	01-09-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-09-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-11-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	26-02-2015
Application type:	Amendment
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	EUCTR2014-002649-24-NL
CCMO	NL50489.056.14