A Two-Stage Phase 1 Repeat Dose Study of BaroFeron* (Recombinant Human Interferon beta-1b) Compared to Betaferon® for Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics After Subcutaneous Administration in Healthy Volunteers

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Study Stage 1:To evaluate the safety and tolerability of BaroFeron administered subcutaneously (SC)To determine the PK and PD profiles of BaroFeron administered SC and compare to Betaferon administered SCTo evaluate evidence of activity of BaroFeron...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Interventional

Summary

ID

NL-OMON32092

Source
ToetsingOnline

Brief title
Two-stage phase 1 study with BaroFeron* and BetaFeron®

Condition

- Central nervous system infections and inflammations

Synonym
Relapse-remitting Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: BaroFold, Inc.
Source(s) of monetary or material Support: BaroFold;Inc.

Intervention

Keyword: Pharmacodynamics, Pharmacokinetics, Recombinant Human Interferon beta-1b, Safety

Outcome measures

Primary outcome

Adverse events, pharmacokinetics, pharmacodynamics

Secondary outcome

not applicable

Study description

Background summary

BaroFeron*, a recombinant human interferon beta-1b (rhIFN beta-1b) product developed by BaroFold, Inc., is being evaluated as a potential drug for the treatment of relapse-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical exacerbations. Current treatments, such as the use of the approved drug Betaferon®, are focused on slowing the progression of the disease for which there is currently no known cure. The active pharmaceutical ingredient (rhIFN beta-1b) in BaroFeron is chemically identical (i.e. the same amino acid sequence) to the active pharmaceutical ingredient in Betaferon. Betaferon is formulated with human serum albumin (HSA) and contains only 40% monomeric rhIFN beta-1b with the remainder as aggregates or HSA complexes. BaroFeron does not contain HSA and is >99% monomeric rhIFN beta-1b. It is expected that the absence of significant rhIFN beta-1b aggregates in BaroFeron will result in significantly lower immune responses in patients compared to Betaferon. By reducing or eliminating the immune response to rhIFN beta-1b, BaroFeron should provide the clinical benefits of prolonged efficacy and safety for RRMS patients who presently require high dose therapy with Betaferon.

Study objective

Study Stage 1:
To evaluate the safety and tolerability of BaroFeron administered subcutaneously (SC)
To determine the PK and PD profiles of BaroFeron administered SC and compare to Betaferon administered SC
To evaluate evidence of activity of BaroFeron by measurement of two or more PD markers and compare to the activity of Betaferon

Study Stage 2:
To compare the safety and tolerability of SC administered BaroFeron and Betaferon within the same subjects
To compare the PK and PD profiles of SC administered BaroFeron and Betaferon within the same subjects

Study design

Part 1: Partially open label, partially double blind, randomised, dose escalation
Part 2: Double blind, randomised, cross-over

Intervention

Part 1:
Group 1 - 0.12mg BaroFeron
Group 2 - 0.25 mg BaroFeron or 0.5mg Betaferon
Group 3 - 0.5 mg BaroFeron or 0.5mg Betaferon

Part 2:
0.5mg BaroFeron or 0.5mg Betaferon (cross-over)

Study burden and risks

De risks during this trial are the possible side effects related to the study medication.
Also the admission period, venapunctures and placing of the canula may cause a burden to the volunteers.

Other assesments taking place during this trial: physical examination, vital signs, blood and urine collection, pregnancy test (only for women), drugscreen, alcoholtest, study restrictions and completion of the pain questionnaire (if applicable)

All volunteers are being monitored by experienced physicians and study

personell

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

• Age 18 to 65 years • Body Mass Index (BMI) between 18 and 28 • Negative serum pregnancy test for females of childbearing potential • Good state of health as determined by medical history, physical examination, vital signs measurement, ECG recording, and clinical laboratory tests • Willing and able to give informed consent

Exclusion criteria

• Subjects who have received treatment for any illness within 30 days of the first study drug dosing • Any active viral, bacterial or systemic fungal infection within one week of enrollment • Documented history of or current cardiovascular, renal, hepatic, or immune disorders • Liver enzymes outside laboratory normal range • Drug or alcohol use within 1 week of study entry • Positive drugs screen or alcohol breath test at screening or at admission • Immunotherapy or immunosuppressant treatment within 4 months prior to study entry • Chronic use of NSAIDs within 1 week prior to study entry • History of multiple sclerosis, optic neuritis, or myelitis • Positive serology for Hepatitis B (HBV), Hepatitis C (HCV), or HIV. Must also have no prior history of HBV or HCV virus infection • Prior history of cancer excluding adequately treated basal cell carcinoma of the skin or adequately treated in situ carcinoma of the cervix • Women who are breastfeeding • Unwilling to use an effective method of contraception while on study • Unwilling to abstain from drug, alcohol and cigarette use during study participation • Any prior treatment with interferon alpha (IFN-alpha) or interferon beta (IFN-beta) therapy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2008
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	BaroFeron
Product type:	Medicine

Brand name:	BetaFeron
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-05-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-06-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-08-2008
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	27-08-2008
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	EUCTR2008-003063-39-NL
CCMO	NL23383.040.08