A Phase I, Randomized, Double-Blind, Parallel Group, Single-Dose Trial to Compare the Pharmacokinetics, Safety, Tolerability and Immunogenicity of Two Formulations of MSB11022 (Proposed Adalimumab Biosimilar)

Published: 26-09-2016
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The primary objective is to investigate and compare the pharmacokinetic (PK) of MSB11022 acetate versus MSB11022-citrate in healthy subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43181

Source
ToetsingOnline

Brief title
EMR200588-003

Condition

- Other condition

Synonym
anti inflammation, biosimilar

Health condition

Healthy Volunteers (arthritis, skin conditions, digestive disorders)

Research involving
Human

Sponsors and support

Primary sponsor: Merck
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Biosimilar, phase 1

Outcome measures

Primary outcome

Concentration of IMP in blood over time

Maximum concentration of IMP in blood reached

Concentration of IMP in blood over time until no longer detectable

Secondary outcome

- Various time-dependent PK measurements of IMP concentration in blood

- Vital signs

- Blood chemistry

- Emergence of AEs and SAEs

- Assessment of development of anti-drug and neutralising antibodies

Study description

Background summary

MSB11022 is a proposed biosimilar to adalimumab (Humira®). To establish biosimilarity, the candidate biosimilar compound must be similar to the reference product, notwithstanding minor differences in clinically inactive components, and there must be no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product (Food and Drug Administration [FDA] Guidance for

Industry. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product 2015) Development of a biosimilar generally includes a comparison of the proposed product and the reference product with respect to structure, function, human pharmacokinetic (PK), clinical immunogenicity, and clinical safety and effectiveness.

Study objective

The primary objective is to investigate and compare the pharmacokinetic (PK) of MSB11022 acetate versus MSB11022-citrate in healthy subjects.

Study design

This is a Phase I, randomized, double-blind, 2 arm, parallel group, single-dose study. The study will evaluate the PK, safety, tolerability, and immunogenicity of 2 formulations of MSB11022: MSB11022-acetate versus MSB11022 citrate.

Intervention

On Day -1, subjects will be admitted to the study site and will remain resident at the study site until Day 8 (after completion of the Day 8 assessments). Subjects will be randomized on Day 1 and will receive a single 40 mg dose of MSB11022-acetate or MSB11022-citrate administered by subcutaneous injection in the lower abdomen (at least 2 inches (5 cm) from the umbilicus). Blood samples for PK analysis will be collected predose (0 hour) and at scheduled time points up to Day 71 postdose. Subjects will be monitored for safety up to Day 71 postdose.

Study burden and risks

In the Phase I EMR200588-001 study, PK equivalence between the MSB11022-citrate formulation, US-RP, and EU-RMP was demonstrated. Safety, tolerability, and immunogenicity profiles were similar between subjects receiving MSB11022 and US-RP or EU RMP. These results establish the PK element of the scientific bridge between all 3 products to justify the relevance of data obtained using EU RMP to support a demonstration of biosimilarity to US-RP.
The purpose of this Phase I clinical study is to compare the PK, safety, immunogenicity, and tolerability of the MSB11022-acetate formulation versus the MSB11022-citrate formulation, both administered by prefilled syringe (PFS) in healthy subjects.

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 and female subjects, 18 to 55 years of age, who are on adequate contraception and are willing and able to comply with the scheduled study visits, investigational medicinal product administration, laboratory tests, and all other study procedures will be eligible for participation in the study.
Other protocol-defined inclusion criteria could apply.

Exclusion criteria

- A history and/or current presence of clinically significant atopic allergy, hypersensitivity or allergic reactions
- Having active or latent tuberculosis or a history of tuberculosis
- Having a lifetime history of invasive systemic fungal infections or other opportunistic infections, chronic or recurrent infections
- Having previously been treated with adalimumab or taken a recombinant monoclonal antibody, or having received a live vaccine within 12 weeks before enrolling in this study or

planning for any such
vaccination during the study or within 4 months after study drug administration.
Other protocol-defined exclusion criteria could apply

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MSB11022
Generic name:	Adalimumab

Ethics review

Approved WMO

Date:	26-09-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	11-10-2016
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	EUCTR2016-003263-19-NL
CCMO	NL58991.056.16