A Phase 1 Multiple Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of IV SYNT001 in Healthy Volunteers.

Published: 25-09-2018
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Primary objectives* To evaluate the safety and tolerability of multiple SYNT001 loading and maintenance doses in healthy subjects.* To determine the multiple dose pharmacokinetics (PK) of SYNT001 in healthy subjects.Secondary objectives* To evaluate...

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

Summary

ID

NL-OMON45830

Source
ToetsingOnline

Brief title
CS0307

Condition

- Autoimmune disorders

Synonym
autoimmune disorder, blister disease

Research involving
Human

Sponsors and support

Primary sponsor: Syntimmune
Source(s) of monetary or material Support: Syntimmune Inc.

Intervention

Keyword: Pharmacodynamics, Pharmacokinetics, Safety, Tolerability

Outcome measures

Primary outcome

Safety parameters including: Treatment Emergent Adverse Events (TEAE), adverse events (AE), Dose Limiting Toxicity (DLT), vital signs (blood pressure and pulse rate), physical examination, 12-lead ECG parameters and clinical laboratory values (hematology, total IgG, serum biochemistry, coagulation, urinalysis, urine microscopy).

PK parameters including: t1/2, Cmax, Tmax, AUC0-24h, AUC0-Tlast, AUC0-*, and CL and Vd (if feasible).

Secondary outcome

PD parameters including: absolute serum levels and percent change from baseline of total IgG, IgG subtypes (IgG1-4), immunoglobulin A (IgA), immunoglobulin M (IgM), albumin, and circulating immune complexes (CIC).

PD immunogenicity parameters including: the presence of anti SYNT001 binding antibodies and neutralizing antibodies.

Study description

Background summary

SYNT001, a humanized, affinity-matured IgG4-kappa monoclonal antibody (mAb),

blocks immunoglobulin G (IgG) and IgG immune complex (IC) interactions with the neonatal crystallizable fragment receptor (FcRn) and thereby inhibits the varied roles played by FcRn in immune response.

Study objective

Primary objectives
* To evaluate the safety and tolerability of multiple SYNT001 loading and maintenance doses in healthy subjects.
* To determine the multiple dose pharmacokinetics (PK) of SYNT001 in healthy subjects.

Secondary objectives
* To evaluate the effect of SYNT001 on pharmacodynamic (PD) biomarkers following multiple loading and maintenance doses in healthy subjects.
* To measure the immunogenicity of SYNT001 in healthy subjects following multiple loading and maintenance doses in healthy subjects.

Exploratory objective
* Additional PK/PD and statistical analyses may be performed.

Study design

This is a Phase 1, single center, double-blind, placebo-controlled, randomized study to evaluate the safety, tolerability, PK, and PD of multiple doses of SYNT001 in healthy male and female (non-child-bearing potential) volunteers.

Intervention

SYNT001 and placebo solution (D5W).

Study burden and risks

The dosage levels of the study drug are based on a previous clinical trail conducted by the sponsor. The risk to health at the chosen dose is limited, but the patients may experience any of the side effects in the ICF or symptoms that have not been reported before. Volunteer health is closely monitored during the study to minimize the risks. If the volunteers experience side effects, the investigator will treat them when necessary. If new information is available on the safety of the study medication, the volunteers are informed as soon as possible. The blood collection procedure is not dangerous.

Contacts

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Syntimmune

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Signed and dated informed consent form indicating the subject has read and understands the protocol and is willing to comply with all aspects of the study.
Male or female subject (non-childbearing potential) between the ages of 18 and 55 years, inclusive, at the time of screening.
Body mass index (BMI) range of 18.0 to 30.0 kg/m2 and body weight range of >50 kg to <120 kg.;For more inclusion criteria, please refer to protocol

Exclusion criteria

Contraindication and/or history of allergic or anaphylactic reactions to study drugs or its excipients.

Positive drug and alcohol test at Screening or on Day -1.
Any vaccination within 2 weeks of Screening.;For more exclusion criteria, please refer to protocol

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):	05-11-2018
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	09-11-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	26-02-2019
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	EUCTR2018-003380-60-NL
CCMO	NL67453.056.18