Phase I, Single-Center, Randomized, Placebo-Controlled, Double-Blinded Study with Single Ascending Doses, Evaluating the Safety and Tolerability of T20K, Administered by a 1-hr IV Infusion in Healthy Male Volunteers

Published: 11-06-2019
Last updated: 10-04-2024

Primary objective: To determine the safety and tolerability of single ascending i.v. doses of T20K administered to healthy male subjects up to detectable levels of T20K within the defined dose rangeSecondary objective: To explore the plasma profile...

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

Summary

ID

NL-OMON48273

Source
ToetsingOnline

Brief title
CS0312 Cyxone

Condition

- Demyelinating disorders

Synonym
Multiple Sclerosis, relapsing-remitting MS

Research involving

Human

Sponsors and support

Primary sponsor: Cyxone AB
Source(s) of monetary or material Support: Cyxone

Intervention

Keyword: MS, Safety, T20K, Tolerability

Outcome measures

Primary outcome

Safety and tolerability parameters including adverse events (AEs), vital signs,

physical examination, 12-lead ECG, telemetry, local tolerance and clinical

laboratory values after single ascending dose administration.

Secondary outcome

Plasma concentrations of T20K.

Study description

Background summary

Cyclotide-based peptides appear to be good candidates for pharmaceutical drug development for treatment of diseases with an overreactive immune system. The reversible T-cell inhibition mechanism of cyclotides makes them very appealing from an efficacy and safety perspective, and it is likely that such products will hold a very competitive position on the multiple sclerosis (MS) market.

Study objective

Primary objective:
To determine the safety and tolerability of single ascending i.v. doses of T20K administered to healthy male subjects up to detectable levels of T20K within the defined dose range

Secondary objective:
To explore the plasma profile of T20K at the first dose level where T20K can

be quantified following i.v. doses of T20K.

Study design

This study is an interventional, single site, placebo-controlled, double-blind, randomized, single ascending dose study.

Intervention

T20K or placebo, single dose.

Study burden and risks

Since the study is being executed in healthy volunteers, there are no anticipated benefits of the IMP. Please see the IMPD for further information.

Contacts

Public
Cyxone AB

Adelgatan 21
Malmö 211 22
SE
Scientific
Cyxone AB

Adelgatan 21
Malmö 211 22
SE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

1. Male subject between 18 and 55 years, inclusive, at the time of screening.
2. Healthy as determined by the Investigator, based upon a medical evaluation including medical history, physical examination and clinical laboratory testing performed at Screening.
3. A body weight of *60 kg and a body mass index (BMI) *18.0 kg/m2 and * 30.0 kg/m2 at Screening.

Exclusion criteria

1. Evidence of active and/or chronic disease that, in the Investigator*s opinion, could interfere with the study procedures or could adversely affect the safety of the subject or could affect the safety and/or pharmacokinetic (PK) evaluations.
2. History of drug abuse.
3. Positive urine drug screen and/or positive alcohol breath test at Screening or on Day -1.

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):	12-07-2019
Enrollment:	40

Type:	Actual

Ethics review

Approved WMO Date:	11-06-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-06-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-07-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-07-2019
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	EUCTR2019-002235-29-NL
CCMO	NL70279.056.19