# 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...

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| **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**
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## 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

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|---|---|
| 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

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| 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 |