Phase 1, randomized, placebo controlled, double blind, single dose-escalation study assessing the safety, tolerability, pharmacokinetics and pharmacodynamics of intravenous IQNLF in healthy subjects.

Published: 02-12-2010
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To investigate the safety and tolerability of the intravenously applied (directly given into a blood vessel) new test compound.

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

Summary

ID

NL-OMON36585

Source
ToetsingOnline

Brief title
IQNLF

Condition

- Bacterial infectious disorders

Synonym
Anthrax, Bacillus anthracis

Research involving
Human

Sponsors and support

Primary sponsor: IQ Therapeutics
Source(s) of monetary or material Support: IQ therapeutics

Intervention

Keyword: Double blind, Healthy subjects, Randomized, Single dose-escalation study

Outcome measures

Primary outcome

To investigate the safety and tolerability of the intravenously applied

(directly given into a blood vessel) new test compound.

Secondary outcome

- To study how the test compound is absorbed, broken-down and excreted by the

body.

- To study the effect of new test compound on the body.

Study description

Background summary

The test compound is a drug that is being developed for the treatment of anthrax.

Study objective

To investigate the safety and tolerability of the intravenously applied (directly given into a blood vessel) new test compound.

Study design

Phase 1, randomized, placebo controlled, double blind, single dose-escalation study.

Intervention

36 healthy male and female volunteers will participate in the trial. 32 men and women will receive an infusion once of 0.5, 1, 2.5 or 7.5 test compound per kilo body weight or placebo.

Study burden and risks

The test medication has not been previously tested in humans but was extensively tested in animals. In these animal models multiple dosing were given and no side effects were seen. However unknown side effects or allergic reactions can never be excluded.

The dose levels are selected on the basis of research results in animals and humans. The risk to health at these dose levels is limited but you may experience one of the above mentioned side-effects or other symptoms not previously reported. Your health will be closely monitored during the trial to minimize these risks.

Contacts

Public
IQ Therapeutics

Rozenburglaan 13a
9727 DL Groningen
NL
Scientific
IQ Therapeutics

Rozenburglaan 13a
9727 DL Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male and female subjects, aged between 18 and 55, BMI 18 to 30 kg/m2

Exclusion criteria

Clinical significant abnormalities during medical research

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):	22-02-2011
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

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	EUCTR2010-023581-42-NL
CCMO	NL34458.056.10