Assessment of the safety and kinetics of IQNLF.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20298

Source
NTR

Health condition

IQNLF is a human antibody which can help in overcoming inhalation antrhax. Anthrax is caused by exposure to Bacillus anthracis, a spore forming bacterium. The infection can be lethal, especially when the spores are inhaled.

Sponsors and support

Primary sponsor: IQ Therapeutics
Rozenburglaan 13a
9727 DL Groningen
The Netherlands
Source(s) of monetary or material Support: IQ Therapeutics
Rozenburglaan 13a
9727 DL Groningen
The Netherlands

Intervention

Outcome measures

Primary outcome

Safety and tolerability of intravenous administered IQNLF in healthy subjects.

Secondary outcome

Pharmacokinetics, pharmacodynamics and immunogenticity of intravenous administered IQNLF in healthy subjects.

Study description

Background summary

The study evaluates the safety and kinetics of a human antibody against anthrax. The results will help in further development of a life-saving drugs against inhalation anthrax infections.

Study objective

Determine safety and kinetics of IQNLF in humans.

Study design

Volunteers will be tested periodically during a period of 90 days after receiving a single dosis. Testing occurs during the first 24 hours and after day 7, 14, 28, 42, 56 and 91 days.

Testing involves vital signs and laboratory parameters.
Pharmacokinetic and immunogenicity parameters will be tested as well.

Intervention

The effect of IQNLF will be compared with placebo control. Treatment involves a single i.v. administration.

Contacts

Public
IQ Therapeutics
Rozenburglaan 13a
Hans Hektor
Groningen 9727 DL
The Netherlands
Scientific
IQ Therapeutics

Rozenburglaan 13a
Hans Hektor
Groningen 9727 DL
The Netherlands

Eligibility criteria

Inclusion criteria

1. Male or female subjects;

2. Aged between 18 and 55;

3. No active, significant, acute or chronic illness.

Exclusion criteria

1. History of any (investigational) anthrax therapy;

2. Excessive alcohol consumption;

3. Known hypersensitivity to excipients;

4. Smoking more than 10 cigarettes or equivalent per day.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2011
Enrollment:	32
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-02-2011
Application type:	First submission

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
NTR-new	NL2628
NTR-old	NTR2756
Other	IQ Therapeutics : TCL10-01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A