

A phase I study to assess safety and tolerability and neutralising activity of CL184 in healthy volunteers

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
27/03/2007	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
10/05/2007	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
01/09/2021	Infections and Infestations	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

MDS Pharma Services

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United States of America

NE68502

Additional identifiers

Protocol serial number

RAB-M-A001

Study information

Scientific Title

A phase I study to assess safety and tolerability and neutralising activity of CL184 in healthy volunteers

Study objectives

First time in human study of CL184, a human monoclonal antibody cocktail against rabies virus.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the MDS Pharma Services Institutional Review Board on the 22nd November 2006.

Study design

1: three cohorts of subjects receive CL184 versus placebo, with increased doses in each cohort

2: one cohort of subjects receive CL184 in combination with rabies vaccine in an open label design

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rabies

Interventions

Part 1: The study subjects will receive one dose of CL184 intramuscularly at Day zero and will be followed up over 42 days.

Part 2: The study subjects will receive one dose of CL184 on Day 0 in combination with rabies vaccine on Days 0, 3, 7, 14 and 28

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

CL184

Primary outcome(s)

Safety and tolerability: this is assessed throughout the study, i.e., over 42 days.

Key secondary outcome(s)

1. Neutralising activity: this analysis is made at Day 14 and at all other timepoints up to Day 42.
2. Pharmacokinetics of CL184: this is a time-dependent parameter and analysis is performed over the full study duration, i.e., 42 days.

Completion date

18/05/2007

Eligibility

Key inclusion criteria

1. Healthy volunteers between 19 and 55 years of age
2. No previous treatment with rabies vaccine
3. Body Mass Index (BMI) between 20 and 28 kg/m²

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

57

Key exclusion criteria

1. Pregnant women, women planning to become pregnant and breastfeeding women
2. A history of or currently active clinically significant cardiac (including clinically significant abnormalities on Electrocardiogram [ECG] according to Principal Investigator [PI]), pulmonary, gastrointestinal, hepatic, renal, pancreatic, or neurological disease

Date of first enrolment

06/12/2006

Date of final enrolment

18/05/2007

Locations

Countries of recruitment

United States of America

Study participating centre

MDS Pharma Services

Lincoln

United States of America

NE68502

Sponsor information

Organisation

Crucell Holland BV (The Netherlands)

ROR

<https://ror.org/04cxegr21>

Funder(s)

Funder type

Industry

Funder Name

Crucell Holland BV (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/11/2008	01/09/2021	Yes	No