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

Submission date	Recruitment status	[_] Prospectively registered
27/03/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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.

Overall study start date
06/12/2006

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/m^2

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
60

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 Servces
Lincoln
United States of America
NE68502

Sponsor information

Organisation
Crucell Holland BV (The Netherlands)

Sponsor details
Archimedesweg 5
Leiden
Netherlands
2333 CN

Sponsor type
Industry

Website
http://www.crucell.com

ROR
https://ror.org/04cxegr21

Funder(s)

Funder type
Industry

Funder Name
Crucell Holland BV (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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