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

Submission date	Recruitment status
10/05/2007	No longer recruiting
Registration date	**Overall study status**
22/06/2007	Completed
Last Edited	**Condition category**
01/09/2021	Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RAB-M-A002

Study information

Scientific Title
A phase Ib study to assess safety and tolerability and neutralising activity of CL184 in healthy volunteers

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from 'Ethics R'US', based in Mumbai (India).

Study design
Randomised, double-blind, placebo controlled, phase Ib study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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 0 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/II

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
02/04/2007

Completion date
08/07/2007

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 18 and 28 kg/m^2

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
44

Total final enrolment
44

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
02/04/2007

Date of final enrolment

08/07/2007

Locations

Countries of recruitment
India

Study participating centre
Dhirubhai Ambani Life Sciences Centre (DALC)
Mumbai
India
400 701

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		17/09/2008	01/09/2021	Yes	No