

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

Submission date
10/05/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/06/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
01/09/2021

Condition category
Infections and Infestations

☐ 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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Contact details

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400 701

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/m²

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