

Study of intravenous PRO 140 or placebo in adult patients with HIV

Submission date
11/02/2008

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
15/02/2008

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
30/12/2020

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

Dr Stephen Morris

Contact details

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United States of America
10591

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PRO140 1302

Study information

Scientific Title

A phase Ib, double-blind, randomized, dose-cohort escalation study of intravenous PRO 140 or placebo in adult patients with HIV-1 infection

Study objectives

The primary efficacy measure is the maximal change from baseline in viral load.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Western Institutional Review Board, 3535 Seventh Ave., SW, Olympia, Washington 98502-5010, USA. Date of approval: 10/04/2005 (ref: 1071726)

Study design

Multi-center, double-blind, randomised, placebo-controlled study.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

HIV-1 infection

Interventions

Participants were randomly allocated to the following four groups (three intervention and one control groups):

Intervention - PRO 140, 10 mg/mL solution for intravenous injection:

Group 1: 0.5 mg/kg single dose

Group 2: 2 mg/kg single dose

Group 3: 5 mg/kg single dose

Control treatment:

Group 4: Placebo, single dose

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

PRO 140

Primary outcome measure

To evaluate the tolerability of a single, intravenous dose of PRO 140 within 59 days

Secondary outcome measures

1. To assess the effect on viral load of ascending single doses of PRO 140 within 59 days
2. To determine the pharmacokinetics of PRO 140 within 59 days

Overall study start date

08/12/2005

Completion date

08/02/2007

Eligibility**Key inclusion criteria**

1. Males and females, at least age 18 years
2. Screening plasma HIV-1 RNA at least 5,000 copies/mL
3. CD4+ count at least 250 cells/mm³ and no documented count equal to or below 200 cells/mm³
4. Subject has not taken any antiretroviral therapy within three months of the screening visit
5. CCR5-tropic virus based on viral tropism assessment at screening visit
6. Normal resting 12-lead electrocardiogram at screening visit
7. Females of childbearing potential must have a negative serum pregnancy test result at screening and a negative urine pregnancy test result recorded within 72 hours prior to the first dose of study drug, and be non-lactating

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Total final enrolment

39

Key exclusion criteria

1. Females who are pregnant or lactating
2. CXCR4-tropic virus or dual-tropic (R5X4) virus based on the Trofile™ assay at the screening visit

3. Previous participation in an experimental drug trial(s) within 30 days of the screening visit
4. History of hepatitis within the previous six months
5. Any prior treatment with any entry, attachment, co-receptor, or fusion inhibitor, investigational or approved

Date of first enrolment

08/12/2005

Date of final enrolment

08/02/2007

Locations

Countries of recruitment

United States of America

Study participating centre

Progenics Pharmaceuticals, Inc.

Tarrytown

United States of America

10591

Sponsor information

Organisation

Progenics Pharmaceuticals, Inc. (USA)

Sponsor details

c/o Dr Stephen Morris

777 Old Saw Mill River Road

Tarrytown

United States of America

10591

Sponsor type

Industry

Website

<http://www.progenics.com>

ROR

<https://ror.org/023ka9926>

Funder(s)

Funder type

Industry

Funder Name

Progenics Pharmaceuticals, Inc. (USA)

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	results	01/11/2008	30/12/2020	Yes	No