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

Submission date	Recruitment status	[_] Prospectively registered
11/02/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Morris

Contact details
Progenics Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown
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