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International randomized controlled phase III trial of DB289 versus pentamidine for the treatment of first stage Human African Trypanosomiasis (HAT)

Submission date
12/07/2005

Registration date
23/08/2005

Last Edited
10/06/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
289-C-010 (C05-010)

Study information

Scientific Title
International randomized controlled phase III trial of DB289 versus pentamidine for the treatment of first stage Human African Trypanosomiasis (HAT)

Study objectives
To compare the efficacy, safety and tolerability of oral DB289 versus intramuscular pentamidine, for treatment of first stage HAT caused by T. b. gambiense.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Human African Trypanosomiasis (HAT) or sleeping sickness

Interventions
The subjects will receive either DB289 or pentamidine treatment according to their randomisation.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
DB289 and pentamidine

Primary outcome measure
The primary efficacy variable will be the combined rate of clinical and parasitological cure at the Test of Cure evaluation (12 month evaluation) in the Per Protocol dataset.

Secondary outcome measures
Parasitological cure, clinical cure, probable relapse, relapse and death rates at the End of Treatment and at the 3, 6, 18 and 24 month evaluations will also be determined.

Overall study start date
15/07/2005

Completion date
15/12/2006

Eligibility

Key inclusion criteria
1. The patient has first stage T. b. gambiense infection, i.e. parasitologically confirmed infection in the blood or lymph node aspirate and White Blood Cell count (WBC) less than or equal to 5 mm^3 detected in the CerebroSpinal Fluid (CSF) by microscopic examination.
2. Patient is male or female 12 years of age or older and more than or equal to 30 kg.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
250

Key exclusion criteria
1. The patient has possible or confirmed second stage T. b. gambiense infection, i.e. presence of parasite in the CSF upon microscopic examination or a WBC count in the CSF of more than 5 mm^-3
2. Active clinically relevant medical conditions that in the Investigator's opinion may jeopardise subject safety or interfere with participation in the study, including but not limited to: significant liver diseases, chronic pulmonary diseases, significant cardiovascular diseases, diabetes, thyroid diseases, gout, infection including known Human Immunodeficiency Virus (HIV) infection, Central Nervous System (CNS) trauma or seizure disorders
3. Coma Score of less than nine on the Glasgow Coma Scale

Date of first enrolment

15/07/2005

Date of final enrolment
15/12/2006

Locations

Countries of recruitment
Angola

Congo

Sudan

Switzerland

Study participating centre
Swiss Tropical Institute
Basel
Switzerland
CH-4002

Sponsor information

Organisation
Immtech Pharmaceuticals, Inc. (USA)

Sponsor details
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Sponsor type
Industry

ROR
https://ror.org/04hxfjk77

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation (USA) - grant ref: 38381

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	16/02/2016		Yes	No