

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	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/08/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2016	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR
<https://ror.org/04hxfjk77>

Funder(s)

Funder type
Charity

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

Results and Publications

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