

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

<b>Submission date</b> 12/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/06/2016	<b>Condition category</b> 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

**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  $5 \text{ mm}^3$  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  $5 \text{ mm}^3$
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?
<a href="#">Results article</a>	results	16/02/2016		Yes	No