

A phase II, randomised, double-blind, placebo-controlled pilot study of the safety, tolerability and activity of intramuscularly administered a-Epi-Br (HE2000) in late stage human immunodeficiency virus-infected patients at risk for opportunistic infections

Submission date 06/04/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 15/05/2006	Overall study status Completed	☐ Protocol
Last Edited 16/10/2009	Condition category Infections and Infestations	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Zoja Noveljic

Contact details

Karl Bremmer Hospital
Cape Town
South Africa
7531

Additional identifiers

Protocol serial number

HE2000-006.4

Study information

Scientific Title

Study objectives

1. To evaluate the safety and tolerability of up to seven treatment courses of 100 mg of HE2000
2. To evaluate the effect of HE2000 on the incidence rate, time to resolution and time to recurrence of opportunistic infections in late stage human immunodeficiency virus (HIV)-infected patients
3. To assess the effect of repeated administrations of HE2000 (a total of 7 treatment courses) on quality of life
4. To assess the effect of HE2000 on the immune system

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Medicines Control Council on 26/09/2000, reference number: N2/19/8/2 (1666)

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Human immunodeficiency virus (HIV)

Interventions

The treatment course consisted of intramuscular injections, once daily for five days, of either 100 mg of HE2000 or placebo in the control group, followed by a 37-day observation period (6 weeks), for up to seven courses

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

HE2000

Primary outcome(s)

To evaluate the safety and tolerability of up to seven treatment courses of 100 mg of HE2000 administered intramuscularly in late HIV patients

Key secondary outcome(s)

The assessment of the effect of HE2000 on the incidence rate of opportunistic infections

Completion date

02/12/2002

Eligibility

Key inclusion criteria

1. HIV-infected patients who are at least 18 years old with a CD4 cell count ≤ 100 cell/mm³ and who are at risk for developing opportunistic infections
2. Karnofsky Performance Score of at least 60 and a life expectancy of at least 6 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients who have received treatment with chemotherapeutic agents within four weeks of study screen
2. Patients receiving immunomodulatory therapies including interferon, interleukins or steroids (e.g. Moducare, testosterone, deca-durabolin, Dehydroepiandrosterone [DHEA], oxandrolone) within four weeks of the screening visit
3. Patients receiving metabolic inhibitors (e.g. hydroxyurea, cyclophosphamide, methotrexate) within four weeks of the screening visit
4. Patients who are deficient in glucose-6-phosphate dehydrogenase (G6PDH) enzyme
5. Patients with an active, opportunistic infection (OI) requiring acute intervention (i.e. hospitalization) within two weeks of screening; (patients undergoing prophylactic OI treatment or completing OI treatment after resolving the acute phase of the infection are permitted entry in the discretion of the investigator)
6. Patients currently diagnosed, with malignancy including invasive cervical cancer (based on pelvic exam and PAP smear), lymphoma (based on observation and patient history), progressive cytomegalovirus (CMV) disease including CMV-retinitis (based on ophthalmic exam including funduscopy, patient history), Kaposi's sarcoma with visceral involvement (based on physical examination and patient history), HIV-encephalopathy and acquired immune deficiency syndrome (AIDS)-related dementia (based on investigators judgment and patient history)
7. Patients who have acute tuberculosis (TB) or malaria based on laboratory results
8. Patients who have malaria (based on laboratory results)
9. Patients with a malignancy other than cutaneous Kaposi's sarcoma (KS) or basal cell carcinoma
10. Patients with biopsy-confirmed cutaneous KS are eligible at the discretion of the investigator
11. Patients must not have received any systemic therapy for KS within four weeks prior to the

screening visit and are not anticipated to require systemic therapy during the course of the study
12. Patients with a clinical condition or receiving therapy that, in the opinion of the investigator, would make the patient unsuitable for study or unable to comply with the dosing requirements
13. Patients who are breast feeding

Date of first enrolment

20/11/2000

Date of final enrolment

02/12/2002

Locations

Countries of recruitment

South Africa

Study participating centre

Karl Bremmer Hospital

Cape Town

South Africa

7531

Sponsor information

Organisation

Hollis-Eden Pharmaceuticals, Inc. (USA)

Funder(s)

Funder type

Industry

Funder Name

Hollis-Eden Pharmaceuticals, Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration