

Clinical epidemiology of Herpes Simplex Virus type two and the impact of interventions against sexually transmitted infections to reduce human immunodeficiency virus incidence in high risk women from gold mining communities in Tanzania

Submission date 22/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/02/2015	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

Study information

Scientific Title

Clinical epidemiology of Herpes Simplex Virus type two and the impact of interventions against sexually transmitted infections to reduce human immunodeficiency virus incidence in high risk women from gold mining communities in Tanzania

Acronym

AMREF HSV Project

Study objectives

The main aim of this trial is to determine whether intervening against herpes simplex virus type 2 (HSV-2) using suppressive therapy with aciclovir will reduce the acquisition of human immunodeficiency virus (HIV) in HIV-negative women and whether suppressive therapy will reduce genital HIV and HSV viral shedding in women who are HIV-infected.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the London School of Hygiene and Tropical Medicine ethics committee and the Medical Research Coordinating Committee of Tanzania

Primary study design

Interventional

Study design

Double-blind randomised placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Human immunodeficiency virus (HIV)

Interventions

A double-blind, randomised, placebo-controlled trial of HSV-2 suppressive therapy with aciclovir 400 mg twice a day (bd), as a strategy to reduce HIV incidence, HSV-2 and HIV viral shedding. The trial is being conducted in a cohort of female bar, guesthouse and other recreational facility workers in goldmining communities and along truck-routes in NW Tanzania.

Please note that this trial has extended follow-up to 30 months for first 1001 participants enrolled and enrolled another 304 participants who will be followed for 12 months. Therefore there is a new anticipated end date of 30th April 2007. The previous anticipated end date was 30/09/2006.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Aciclovir

Primary outcome(s)

HIV acquisition study:

1. HIV incidence by treatment arm
2. Frequency of genital ulceration by treatment arm
3. Adherence to therapy

HIV-positive women at enrolment:

1. Prevalence and quantity (log copies/ml) of cervico-vaginal HIV-1 RNA shedding by treatment arm
2. Plasma viral load by treatment arm
3. Prevalence and quantity of cervico-vaginal proviral HIV-1 DNA shedding
4. Prevalence and quantity of cervico-vaginal HSV-2 DNA shedding
5. Adherence to therapy

Key secondary outcome(s)

No secondary outcome measures

Completion date

30/04/2007

Eligibility**Key inclusion criteria**

1. Aged 16 to 35 years
2. HSV-2 seropositive
3. Not planning to leave study sites within next 24 months
4. No history of epilepsy
5. Able to understand aims and procedures of trial

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Pregnant or planning pregnancy within next 24 months
2. HSV-2 seronegative or indeterminate

3. Breastfeeding at time of enrolment
4. History of epilepsy
5. Temporary visitor in study sites
6. Unable to give informed consent

Date of first enrolment

01/10/2003

Date of final enrolment

30/04/2006

Locations

Countries of recruitment

United Kingdom

England

Tanzania

Study participating centre

London School of Hygiene and Tropical Medicine

London

United Kingdom

WC1E 7HT

Sponsor information

Organisation

London School of Hygiene and Tropical Medicine (UK)

ROR

<https://ror.org/00a0jsq62>

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

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	10/04/2008		Yes	No
Results article	results	01/09/2009		Yes	No
Results article	results	01/05/2010		Yes	No