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# 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 | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 22/07/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 22/07/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 06/02/2015 | Infections and Infestations | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Deborah Watson-Jones

**Contact details**
London School of Hygiene and Tropical Medicine
Department of Infectious and Tropical Diseases
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7927 2116
deborah.watson-jones@lshtm.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
066688

# 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

### Study design
Double-blind randomised placebo-controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
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

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
01/10/2003

### 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

### Age group
Adult

### Sex
Female

### Target number of participants
1305

### 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
England

Tanzania

United Kingdom

### 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)

### Sponsor details
Research Grants and Contracts Office
Keppel Street
London
England
United Kingdom
WC1E 7HT
+44 (0)20 7827 2678
Penny.Ireland@lshtm.ac.uk

### Sponsor type
University/education

### Website
http://www.lshtm.ac.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

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