ISRCTN35385041 https://doi.org/10.1186/ISRCTN35385041

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

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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
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United Kingdom
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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