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A randomized placebo controlled trial of a combination of acyclovir, benzathine penicillin and ciprofloxacin versus a combination of placebo, benzathine penicillin and ciprofloxacin for the syndromic treatment of genital ulcer disease in Malawi

Submission date	Recruitment status	[_] Prospectively registered
27/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/06/2014	Urological and Genital Diseases	

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
04-MED-388

Study information

Scientific Title

Study objectives
Control of Sexually Transmitted Infections (STI), including Genital Ulcer Disease (GUD), has been established as an important strategy for the prevention of Human Immunodeficiency Virus (HIV) transmission. Studies have shown that GUD causes an increase in the concentration of HIV-RNA (RiboNucleic Acid) in ulcer lesions and semen, which may increase HIV transmissibility, and which is reversible with GUD treatment.

As recommended by the World Health Organization for resource poor countries, a syndromic approach to managing patients with genital ulcers is utilized in Malawi. Based on data from the early 1990s, the current syndromic management of GUD is designed to treat syphilis and chancroid only. More recent data from Lilongwe Central Hospital in Malawi, however, shows that as many as 35% of patients presenting to the Sexually Transmitted Disease (STD) clinic with GUD are infected with genital herpes. HIV seroprevalence rates are well over 50% among these genital ulcer patients. Although there is no cure for genital herpes, treatment with anti-herpetic agents can have a significant effect on its management. In addition, recent changes in the availability and price of selected anti-herpetic agents make it an affordable option for many countries as a component in the treatment of genital ulcers.

Through a randomized double blinded, placebo controlled trial, this investigation will determine if adding the anti-herpetic agent, acyclovir, to the current syndromic management of GUD improves the cure rate of genital ulcers. In addition, it will determine whether treatment with acyclovir will affect the levels of HIV-RNA in the genital secretions and blood of men and women co-infected with HIV and Herpes Simplex Virus (HSV).

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

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Genital Ulcer Disease (GUD)

Interventions
A combination of acyclovir, benzathine penicillin and ciprofloxacin versus a combination of placebo, benzathine penicillin and ciprofloxacin

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Acyclovir, benzathine penicillin, ciprofloxacin

Primary outcome(s)
1. To determine if the addition of acyclovir for the treatment of genital herpes will improve the cure rate of the current syndromic management for GUD in Malawi

2. To determine if HIV status affects this cure rate

Key secondary outcome(s))
1. To determine if GUD management, with and without treatment for genital herpes, affects the level of HIV-RNA in the blood, ulcer lesion as well as genital secretions of HIV-infected patients with GUD and whether this is related to cure rate

2. To assess the incremental cost benefit for the addition of acyclovir to the current syndromic treatment of GUD

Completion date
01/01/2006

Eligibility

Key inclusion criteria
1. Age 18 years or older

2. Clinically confirmed genital ulcer(s)

3. Ability to provide informed consent for participation, examination and sample collection

4. Willingness to be counselled

5. Tested and received results for HIV and other STIs

6. Resident in Lilongwe catchments area and with intention to stay for at least one month

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Younger than 18 years old

2. Known allergy to penicillin, erythromycin, acyclovir, or ciprofloxacin

3. Patients with known or evidence of renal impairment

4. Very sick requiring admission

5. Women currently menstruating

6. Pregnant or lactating mothers

Date of first enrolment
01/09/2004

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
Malawi

United States of America

Study participating centre
Center for Infectious Diseases
Chapel Hill
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27599-3368

Sponsor information

Organisation
University of North Carolina (USA)

ROR
https://ror.org/0130frc33

Funder(s)

Funder type
Government

Funder Name
National AIDS Commission

Funder Name
Malawi Ministry of Health, Lilongwe, Malawi

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	01/12/2013		Yes	No