ISRCTN47258104 https://doi.org/10.1186/ISRCTN47258104

Male circumcision to reduce human immunodeficiency virus (HIV) incidence in Kenya

Submission date	Recruitment status	[_] Prospectively registered
01/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/02/2009	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
https://unim.rti.org/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00059371

Secondary identifying numbers
MCT-44180

Study information

Scientific Title
A randomised, controlled trial of male circumcision to reduce human immunodeficiency virus (HIV) incidence in Kisumu, Kenya

Acronym
UNIM

Study objectives
1. To assess the effectiveness of male circumcision in reducing human immunodeficiency virus (HIV) incidence among young men in Kisumu, Kenya
2. To evaluate any adverse clinical effects of the circumcision procedure
3. To evaluate differences in sexual behaviour, perceptions of sexual function and sexual pleasure between men who are uncircumcised and circumcised
4. To evaluate the biological mechanisms by which presence of the foreskin increases HIV susceptibility

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Boards of:
1. Biomedical Research Ethics Board, University of Manitoba approved on the 20th March 2001
2. Kenyatta National Hospital approved on the 26th March 2001

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
Male circumcision (surgical removal of prepuce) versus no circumcision.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
HIV seroconversion

Secondary outcome measures
1. Incidence of sexually transmitted infections
2. Sexual behaviour change
3. Complications of the circumcision procedure

Overall study start date
01/02/2002

Completion date
31/10/2007

Eligibility

Key inclusion criteria
Participating men must be:
1. Uncircumcised
2. Sexually active
3. Aged 18 - 24 years inclusive
4. Resident in Kisumu district with no plans to move away for the duration of follow-up
5. Agreeable to returning for follow-up as required by the study protocol, including periodic HIV testing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
2776

Key exclusion criteria

Men are excluded if they are:
1. Circumcised
2. Sexually active
3. Outside the indicated age range
4. Not resident in Kisumu or surroundings, or unlikely to remain there for the follow-up period
5. Unwilling to conform to the follow-up protocol
6. Having haemophilia or other bleeding disorders, or other medical conditions for which a surgical procedure is contra-indicated

Date of first enrolment
01/02/2002

Date of final enrolment
31/10/2007

Locations

Countries of recruitment
Canada

Kenya

Study participating centre
University of Manitoba
Winnipeg, Manitoba
Canada
R3E 0W3

Sponsor information

Organisation
University of Manitoba (Canada) - Department of Medical Microbiology

Sponsor details
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Sponsor type
University/education

Website

http://www.umanitoba.ca/

ROR
https://ror.org/02gfys938

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-44180)

Funder Name
National Institutes of Health (USA)

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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	24/02/2007		Yes	No