

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

Submission date 01/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/02/2009	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

ClinicalTrials.gov (NCT)
NCT00059371

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

HIV seroconversion

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

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

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Sponsor information

Organisation

University of Manitoba (Canada) - Department of Medical Microbiology

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)

US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/02/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes