

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

Submission date
01/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
01/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
26/02/2009

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<https://unim.rti.org/>

Contact information

Type(s)

Scientific

Contact name

Dr Stephen Moses

Contact details

University of Manitoba
Department of Medical Microbiology
Room 503, Basic Medical Sciences Bldg.
730 William Avenue
Winnipeg, Manitoba
Canada
R3E 0W3
+1 204 789 3357
smoses@cc.umanitoba.ca

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

730 William Avenue

Winnipeg, Manitoba

Canada

R3E 0W3

+1 204 789 3357

smoses@cc.umanitoba.ca

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