ClinicalTrials.gov
Simplifying the Shang Ring Technique for Circumcision of Men and Boys

This study is currently recruiting participants. (see Contacts and Locations)

Verified January 2016 by EngenderHealth

Sponsor:
EngenderHealth

Collaborators:
Weill Medical College of Cornell University
Bon Sante Consulting Limited
Kenya National AIDS & STI Control Programme
Kenya Ministry of Health

Information provided by (Responsible Party):
EngenderHealth

ClinicalTrials.gov Identifier:
NCT02390310

First received: February 5, 2015
Last updated: January 25, 2016
Last verified: January 2016

Purpose
This is a research study in Kenya that will examine the outcomes of participants aged 10-15 and 16 and older; and provider acceptability of the Shang Ring technique for male circumcision that would simplify use. The study will be in two phases:

Phase 1 will explore the no-flip technique that has been used in China but will be used for the first time in Africa.

Phase 2 will be a randomized trial comparing use of tropical vs. injectable anesthesia.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Human Immunodeficiency</td>
<td>Device: Shang Ring</td>
</tr>
<tr>
<td>Virus</td>
<td>Drug: injectable anesthesia (lidocaine 1%)</td>
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<td></td>
<td>Drug: topical anesthesia (lidocaine 2.5%, prilocaine 2.5%)</td>
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</table>
Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Prevention

Official Title: Simplifying the Shang Ring Technique for Circumcision of Men and Boys

Further study details as provided by Engender Health:

Primary Outcome Measures:
• Phase I: Combined rate of moderate and severe adverse events (AEs) as a measure of safety of the no-flip technique for Shang Ring circumcision in males aged 10 years and older [ Time Frame: 42 days ] [ Designated as safety issue: Yes ]
We will evaluate the rate of moderate and severe AEs (combined) following Shang Ring MC using the no-flip technique based on clinical exam findings.

• Phase 2: Pain measured with the visual analogue scale (VAS) experienced during the Shang Ring circumcision procedure with topical (EMLA Cream; lidocaine 2.5% and prilocaine 2.5%) vs. injectable (1% lidocaine) anesthesia. [ Time Frame: 42 days ] [ Designated as safety issue: No ]
The outcome metric for the primary outcome will be maximum pain reported to have been experienced by participants during the Shang Ring circumcision, assessed using the visual analogue scale (VAS), reported immediately after completion of the Shang Ring circumcision procedure

Secondary Outcome Measures:
• Phase I: Ease of use of the Shang Ring with the no-flip technique as measured by MC procedure and device removal times and problems encountered during MC and removal procedures [ Time Frame: 42 days ] [ Designated as safety issue: No ]
To evaluate ease of use with the no-flip technique we will document MC procedure and device removal times and problems encountered during MC and removal procedures

- Phase I: Satisfaction of the no-flip Shang Ring among study participants [Time Frame: 42 days] [Designated as safety issue: No]
  - we will interview participants/parents/guardians to document acceptability and satisfaction with the Shang Ring circumcision, procedure and post-procedure pain, and time to return to normal activity

- Phase I: Occurrence of spontaneous detachment among those participants wearing the Shang Ring for more than 7 days after circumcision [Time Frame: 42 days] [Designated as safety issue: Yes]
  - we will gather data on timing of spontaneous detachment among those participants wearing the Shang Ring for more than 7 days after circumcision

- Phase I: Safety of spontaneous detachment as measured by AEs among those participants wearing the Shang Ring for more than 7 days after circumcision [Time Frame: 42 days]
  - we will gather data to document AEs among those participants wearing the Shang Ring for more than 7 days after circumcision

- Phase 2: Safety of topical vs. injectable anesthesia for local anesthesia during Shang Ring circumcision as measured by rates of moderate and severe AEs (combined rates) [Time Frame: 42 days] [Designated as safety issue: Yes]
  - we will document rates of moderate and severe AEs among those having a Shang Ring circumcision with topical vs. injectable anesthesia

- Phase 2: Satisfaction with topical vs. injectable anesthetic among study participants [Time Frame: 42 days] [Designated as safety issue: No]
  - we will interview study participants and their parents/guardians appropriate to document acceptability and satisfaction with the circumcision, the Shang Ring procedure, post-procedure pain, and time to return to normal activity between the two techniques

Estimated Enrollment: 575
**Study Start Date:** May 2015  
**Estimated Study Completion Date:** March 2016  
**Estimated Primary Completion Date:** March 2016 (Final data collection date for primary outcome measure)

<table>
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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</table>
| **Active Comparator: Phase 1 - 7 Day Removal**  
Shang Ring No Flip Technique: Removal of Shang Ring and assessment of healing 7 days after circumcision with no-flip technique. | Device: Shang Ring  
Comparison of healing times at 7 day and more than 7 days after circumcision.  
Other Name: Shang Ring No Flip Technique |
| **Active Comparator: Phase 1 - Delayed Removal**  
Shang Ring No Flip Technique: Removal of ring or assessment of spontaneous detachment at more than 7 days to assess occurrence and safety following circumcision with the no-flip technique. | Device: Shang Ring  
Comparison of healing times at 7 day and more than 7 days after circumcision.  
Other Name: Shang Ring No Flip Technique |
| **Active Comparator: Phase 2 - Topical Anesthesia**  
Comparison of Anesthesia methods for Shang Ring circumcision: Assessment of pain during and after surgery using topical anesthesia. | Drug: topical anesthesia (lidocaine 2.5%, prilocaine 2.5% cream)  
Comparison of Anesthesia methods for Shang Ring circumcision. Comparison of pain during Shang Ring circumcision when using injectable vs. topical anesthesia. |
| **Active Comparator: Phase 2 - Injectable Anesthesia**  
Comparison of Anesthesia methods for Shang Ring circumcision: Assessment of pain during and after surgery when using injectable anesthesia. | Drug: injectable anesthesia (lidocaine 1%)  
Comparison of Anesthesia methods for Shang Ring circumcision. Comparison of pain during Shang Ring circumcision when using injectable vs. topical anesthesia. |

**Detailed Description:**

The study, to be conducted in two phases, will examine procedural and clinical outcomes, as well as participant and provider acceptability, of adaptations of the Shang Ring technique for male circumcision that would simplify its use and increase its acceptability.
Phase I will be non-comparative for exploration of the no-flip technique for Shang Ring circumcision (i.e. all participants will be circumcised using the no-flip Shang Ring technique). Historical data from standard Shang Ring circumcisions conducted in Africa (Kenya, Uganda and Zambia) will be used as the comparison group. Men will be randomized to removal at 7 days after circumcision vs. delayed removal, to assess occurrence and safety of spontaneous detachments following circumcision with the no-flip technique.

Phase 2 will compare the use of topical vs. injectable anesthesia for Shang Ring circumcision. Participants will be randomized to topical vs. injectable anesthesia in a 2:1 ratio. The investigators rationalize the 2:1 randomization scheme given that the investigators will have just completed Phase I in which 200 men and boys will have been circumcised using the no-flip technique with injected anesthesia. However, given the subjectivity associated with using reported pain as the primary endpoint, the investigators believe it is critical to randomize participants in this phase of the study.

**Eligibility**

Ages Eligible for Study: 10 Years and older
Genders Eligible for Study: Male
Accepts Healthy Volunteers: Yes

**Criteria**

Inclusion Criteria:

- Aged 10 years and older;
- Uncircumcised upon clinical examination;
- In good general health;
- Free of genital ulcerations or other visible signs of sexually transmitted infections upon clinical examination;
- Participant and parent or legally acceptable representative (LAR) as applicable must be able to understand study procedures and requirements of study participation;
- Freely consents to participate in the study and signs a written informed consent form if 18 years of age or greater
- Accompanied by the parent/LAR, who freely consents and signs an informed consent form for participation of the child into the study for participants less than 18 years old;
- Assent from participant less than 18 years old who understand study procedure;
- Participant must agree to return to the study site for the full schedule of follow-up visits after his circumcision (or as appropriate the Parent or LAR must agree to bring the participant);
- Participant and parent/LAR as appropriate must agree to provide the study staff with an address, phone number, or other locator information while participating in the research study.
Exclusion Criteria:

- Has a known allergy or sensitivity to lidocaine or other local anesthesia;
- Takes a medication that would be a contraindication for elective surgery, such as an anticoagulant or steroid;
- Has known bleeding/clotting disorder (e.g. hemophilia);
- Has any congenital genitourinary abnormality;
- Has an active genital infection, anatomic abnormality or other condition (e.g. diabetes or sickle cell anemia), which in the opinion of the surgeon, prevents the man from undergoing a circumcision as part of this study; or,
- Is currently participating in another biomedical research study.

**Contacts and Locations**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn about Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02390310

**Contacts**

Contact: Mark A Barone, DVM, MS  212-561-8084  mbarone@engenderhealth.org

**Locations**

**Kenya**

- Homa Bay Level IV County Hospital  **Recruiting**
  Homa Bay, Homa Bay County, Kenya
  Contact: Raymond Otieno

- Vipingo Health Center  **Recruiting**
  Vipingo, Kilifi County, Kenya
  Contact: Judy Kinya

**Sponsors and Collaborators**

EngenderHealth
Weill Medical College of Cornell University
Bon Sante Consulting Limited

Kenya National AIDS & STI Control Programme

Kenya Ministry of Health

Investigators

Principal Investigator:  Mark A Barone, DVM, MS  EngenderHealth

More Information

No publications provided

Responsible Party:  EngenderHealth

ClinicalTrials.gov Identifier:  NCT02390310  History of Changes

Other Study ID Numbers:  OPP1084493

Study First Received:  February 5, 2015

Last Updated:  January 25, 2016

Health Authority:  Kenya: KEMRI

Keywords provided by EngenderHealth:

male circumcision
Shang Ring
male circumcision device
prevention
voluntary medical male circumcision (VMMC)

Additional relevant MeSH terms:

Acquired Immunodeficiency Syndrome  Anti-Arrhythmia Agents
HIV Infections  Cardiovascular Agents
Immunologic Deficiency Syndromes  Central Nervous System Agents
Immune System Diseases  Central Nervous System Depressants
Lentivirus Infections  Membrane Transport Modulators
RNA Virus Infections  Molecular Mechanisms of Pharmacological Action
Retroviridae Infections  Peripheral Nervous System Agents
Sexually Transmitted Diseases  Pharmacologic Actions
Sexually Transmitted Diseases, Viral  Physiological Effects of Drugs
Slow Virus Diseases  Sensory System Agents
Virus Diseases
Anesthetics: Sodium Channel Blockers
Lidocaine: Therapeutic Uses
Anesthetics, Local: Voltage-Gated Sodium Channel Blockers

ClinicalTrials.gov processed this record on March 31, 2016