Pan African Clinical Trials Registry
South African Medical Research Council, South African Cochrane Centre
PO Box 19070, Tygerberg, 7505, South Africa
Telephone: +27 21 938 0506 / +27 21 938 0834     Fax: +27 21 938 0836
Email: pactradmin@mrc.ac.za     Website: www.pactr.org

Trial no.: PACTR201301000465398     Date registered: 2012/11/27
Trial Status: Registered in accordance with WHO and ICMJE standards

TRIAL DESCRIPTION
Public title Early infant male circumcision using devices
Official scientific title Piloting implementation of early infant male circumcision using devices in Zimbabwe
Brief summary describing the background and objectives of the trial A study to assess the feasibility, safety, acceptability and cost of rolling out early infant male circumcision to babies born within selected health facilities in Zimbabwe. Initially a comparative trial of two EIMC devices: AccuCirc and Mogen clamp. The objectives are: 1) To conduct a comparative trial of AccuCirc and Mogen clamp to determine AccuCirc’s relative safety, acceptability and costs.

Type of trial RCT
Acronym (if the trial has an acronym then please provide)

Disease(s) or condition(s) being studied Early infant circumcision ultimately for HIV prevention
Purpose of the trial Prevention
Anticipated trial start date 2013-11-11
Actual trial start date 2013-01-07
Anticipated date of last follow up 2013-05-01
Actual date of last follow up 2013-06-28
Anticipated target sample size (number of participants) 150
Actual target sample size (number of participants)
Recruitment status Not yet recruiting
Publication URL

STUDY DESIGN
Intervention assignment Allocation to intervention If randomised, describe how the allocation sequence was generated Describe how the allocation sequence/code was concealed from the person allocating the participants to the intervention arms Masking If masking blinding was used
Parallel: different groups receive different interventions at same time during study Randomised variable permuted block randomisation (3,6,9) Sealed opaque envelopes Open-label (masking not used)

INTERVENTIONS

<table>
<thead>
<tr>
<th>Intervention type</th>
<th>Intervention name</th>
<th>Dose</th>
<th>Duration</th>
<th>Intervention description</th>
<th>Group size</th>
<th>Natu of contr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental group</td>
<td>Circumcision using AccuCirc</td>
<td>N/A</td>
<td>N/A</td>
<td>Early infant Male Circumcision</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Control group</td>
<td>Circumcision using Mogen clamp</td>
<td>N/A</td>
<td>N/A</td>
<td>Early infant Male Circumcision</td>
<td>50</td>
<td>Active</td>
</tr>
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</table>

ELIGIBILITY CRITERIA

<table>
<thead>
<tr>
<th>List inclusion criteria</th>
<th>List exclusion criteria</th>
<th>Min age</th>
<th>Max age</th>
<th>Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td>Live born male infants at study sites aged 7-10 days. Ability to follow-up regularly at study clinic until 2 weeks postpartum. Mother prepared to provide locator information and to be visited home between delivery and circumcision. Baby should have received vitamin K (routine or offered by study staff).</td>
<td>Neonatal sepsis or other severe illness requiring infant hospitalization. Perinatal abnormality that might require reconstructive surgery in the future. Family history of bleeding disorder. Estimated infant gestational age &lt; 36 weeks. Infant delivery weight &lt; 2,500 grams. Current involuntary incarceration of child.</td>
<td>7 Days</td>
<td>60 Days</td>
<td>Male</td>
</tr>
</tbody>
</table>
ETHICS APPROVAL

Has the study received appropriate ethics committee approval

Date the study will be submitted for approval

Date of approval

Name of the ethics committee

Yes

2012/10/25

Medical REsearch Council of Zimbabwe

Ethics Committee Address

Josiah Tongogara/Mazoe Street

Harare

Zimbabwe

OUTCOMES

Type of outcome

Outcome

Timepoint(s) at which outcome measured

Primary Outcome

Safety - Number of AEs (minor, moderate and severe) related to each EIMC technique

14 days

Primary Outcome

Acceptability - The proportion of parents who report being satisfied with the procedure by EIMC technique

14-36 days

Primary Outcome

Cost - Monetary cost of equipment usage for each technique plus training costs and labour cost associated with EIMC under each technique and the cost of AE under each technique

42 days

Secondary Outcome

Proportion with complete wound healing at 7 and 14 days post circumcision for each EIMC technique

7 days post circumcision 14 days post circumcision

Secondary Outcome

Time required for each EIMC technique

Day of circumcision

Secondary Outcome

Safety stratified by infant HIV exposure status

42 days

Secondary Outcome

Assessment of competency of EIMC using each device

14 days post circumcision

Secondary Outcome

Provider opinions of each device

After recruitment completed

RECRUITMENT CENTRES

Name of recruitment centre

Street address

City

Postal code

Country

Edith Oppermann Clinic

Mbare

Harare

Zimbabwe

FUNDING SOURCES

Name of source

Street address

City

Postal code

Country

Bill and Melinda GatesFoundation

Seattle

United State of America

SPONSORS

Sponsor level

Name

Street address

City

Postal code

Country

Nature of sponsor

Primary Sponsor

Bill and Melinda Gates Foundation

Seattle

United States of America

Population Services International

30 The Chase , Mount Pleasant

Harare

Zimbabwe

Company

COLLABORATORS

Name

Street address

City

Postal code

Country

Dr Gerald Gwinji

Ministry of Health and Child Welfare

Harare

Zimbabwe

Ms Getrude Ncube

Ministry of Health and Child welfare

Harare

Zimbabwe

Mr Webster Mavhu

CeSHHAR Zimbabwe

Harare

Zimbabwe

Mr Christopher Samkange

University of Zimbabwe

Harare

Zimbabwe

Dr Helen Weiss

London School of Hygeine and Tropical Medicine

Chapel Hill

United State of America

Dr Natasha Larke

London School of Hygeine and Tropical Medicine

London

United Kingdom

Intouch Charity

Zimbabwe

Company

Dr nuclei

University of North Carolina

Chapel Hill

United State of America

Dr Dr Harsha

University of North Carolina

Chapel Hill

United State of America

Dr Harsha

University of North Carolina

Chapel Hill

United State of America

 CONTACT PEOPLE

Role

Name

Email

Phone

Fax

Principal Investigator

Dr Ismail Ticklay

ismail4855@gmail.com

+263777005608

Public Enquiries

Mr Webster Mavhu

wmavhu@gmail.com

+263712432215
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<thead>
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<th>STREET ADDRESS</th>
<th>CITY</th>
<th>POSTAL CODE</th>
<th>COUNTRY</th>
<th>POSITION / AFFILIATION</th>
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</thead>
<tbody>
<tr>
<td>21 Rowland Square</td>
<td>Harare</td>
<td>Zimbabwe</td>
<td>Coordinator</td>
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<table>
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<tr>
<td>Scientific Enquiries</td>
<td>Dr Frances Cowan</td>
<td><a href="mailto:f.cowan@ucl.ac.uk">f.cowan@ucl.ac.uk</a></td>
<td>+263(0)772 257949</td>
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<td>Zimbabwe</td>
<td>Co-investigator</td>
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<table>
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<tr>
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<th>TIME</th>
<th>REASON</th>
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<td>2013-06-28</td>
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<td>To align with WHO recommendations</td>
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<td>Training took longer than anticipated</td>
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<td>2013-01-07</td>
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<td>Accrual was slower than anticipated</td>
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