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Pan African Clinical Trials Registry

South African Medical Research Council, South African Cochrane Centre
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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 in 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	

Secondary Ids	Issuing authority/Trial register	Links to Secondary ID

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 permted block randomisation (3,6,9)	Sealed opaque envelopes	Open-label (masking not used)	

INTERVENTIONS

Intervention type	Intervention name	Dose	Duration	Intervention description	Group size	Natu of contr
Experimental group	Circumcision using AccuCirc	N/A	N/A	Early infant Male Circumcision	100	
Control group	Circumcision using Mogen clamp	N/A	N/A	Early infant Male Circumcision	50	Active

ELIGIBILITY CRITERIA

List inclusion criteria	List exclusion criteria	Min age	Max age	Gende
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 Mother prepared to provide verifiable cell phone (mobile) number Provision of written informed consent Baby should have received vitamin K (routine or offered by study staff)	Neonatal sepsis or other severe illness requiring infant hospitalization Penile abnormality that might require reconstructive surgery in the future Family history of bleeding disorder Estimated infant gestational age < 36 weeks (we envisage that this information would be sufficiently and accurately recorded on the child health card by clinic staff) Infant delivery weight < 2,500 grams (we envisage that this information would be sufficiently and accurately recorded on the child health card by clinic staff) Infant >10 days of age Infant receipt of methaemoglobin-inducing agents Current involuntary incarceration of	7 Days	60 Days	Male

	mother			

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

Street address	City	Postal code	Country
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 cirucmcision 14 days post cirucmcision
Secondary Outcome	¿ Time required for each EIMC technique	Day of circumcision
Secondary Outcome	¿ Proportion of babies excluded due to unsuitability for circumcision	Day of enrollment
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 o sponso
Primary Sponsor	Bill and Melinda Gates Foundation		Seattle		United States of America	Foundati
Secondary Sponsor	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
Dr Ismail Ticklay	University of Zimbabwe	Harare		Zimbabwe
Dr Karin Hatzold	PSI Zimbabwe	Harare		Zimbabwe
Dr Frances Cowan	University College London	London	WC1E 6AU	United Kingdom
Mr Christopher Samkange	University of Zimbabwe	Harare		Zimbabwe
Ms Getrude Ncube	Ministry of Health and Child Welfare	Harare		Zimbabwe
Mr Webster Mavhu	CeSHHAR Zimbabwe	Harare		Zimbabwe
Ms Cynthia Chasokela	Director of Nursing Services	Harare		Zimbabwe
Ms Margaret Nyandoro	Ministry of Health and Child welfare	Harare		Zimbabwe
Ms Nontando Mothobi	Registrar Nursing Council	Harare		Zimbabwe
Dr Helen Weiss	London School of Hygeine and Tropical Medicine	London		United Kingdom
Dr Natasha Larke	London School of Hygeine and Tropical Medicine	London		United Kingdom
Dr Harsha Thirumurthy	University of North Carolina	Chapel Hill		United State of America

CONTACT PEOPLE

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21 Rowland Square	Harare		Zimbabwe	Coordinator

Role	Name	Email	Phone	Fax
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21 Rowland Square	Harare		Zimbabwe	Co-investigator

Changes to trial information

Date	Reason	Old Value	Update Value
2013-01-29 10:07:35.0	Modified	RCT	RCT
2013-12-09 16:39:03.0	Slow accrual		2013-06-28
2013-12-10 10:45:32.0	TO align with WHO recommednations	60	60
2013-12-10 10:52:46.0	to align with WHO recommendations	60	60
2013-12-10 10:55:01.0	Training took longer than anticipated		2013-01-07
2013-12-10 10:55:01.0	Accrual was slower than anticipated	150	150