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Uganda Newborn Survival Study: improving newborn health and survival through a community based intervention linked to health facilities

Submission date	Recruitment status	[_] Prospectively registered
31/10/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/02/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/02/2017	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Improving newborn health and survival through a community based intervention linked to health facilities: a randomised controlled cluster trial

Acronym
UNEST

Study objectives
Implementation of an integrated care package of four home visits by a community health worker (CHW) during pregnancy and the neonatal period to deliver one on one health messages and promoting linkage to the health facility improves the following maternal-newborn care practices by at least 20% in two years amongst the target population in rural Uganda.

Further information can be found at:
http://www.ncbi.nlm.nih.gov/pubmed/18570672
http://www.ncbi.nlm.nih.gov/pubmed/19710561

Ethics approval required
Old ethics approval format

Ethics approval(s)
Uganda National Council of Science and Technology HS626 approved from the 20/08/2009 to 20/08/2010

Study design
Randomised controlled cluster trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Maternal and newborn health

Interventions
Through formative research around evidence-based practices, and dialogue with policy and technical advisors, we will construct a home-based neonatal care package implemented by the responsible Village Health Team member, effectively a Community Health Worker. This CHW will be trained to identify pregnant women and make four home visits: two before and two just after birth. Linkages will be made to facility care and targeted messages for home-care and care-seeking delivered. The project will improve care in health units to provide standardised care for the mother and the newborn in both intervention and comparison areas.

The control area is being given the current standard of care provided by the Government. However, health facility quality improvement initiatives are being provided in both control and intervention areas in order to standardise care but also for ethical reasons. This will enable sick newborns in the control area to access care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. In ANC:
1.1. % of pregnant women attending ANC two, four or more times
1.2. % of pregnant women who know at least two danger signs of pregnancy
1.3. % of pregnant women who prepare for birth

2. In the intrapartum period:
2.1. % of pregnant women who have a skilled attendant at delivery
2.2. % of women who went to the HC in an emergency

3. In the post-natal period:
3.1. % of babies who are initiated on breastfeeding in the first 6 hours of birth
3.2. % of babies who are exclusively breastfed during the neonatal period
3.3. % of babies whose first bath was delayed for 6 and 24 hours
3.4. % of mothers who put nothing on the cord
3.5. % of mothers who know at least 3 neonatal danger signs
3.6. % women whose children were managed in skin to skin contact after delivery.
3.7. Effectiveness of sepsis management (special studies to determine: maternal and CHW knowledge, compliance and timing of referral, and adequacy of treatment following referral)

Secondary outcome measures
1. Neonatal mortality
2. Perinatal mortality

Overall study start date
01/07/2009

Completion date

30/12/2011

Eligibility

Key inclusion criteria
1. Women of childbearing age
2. Pregnant women
3. Newly delivered women
4. Neonates and infants

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants
65 villages, 70000 people

Key exclusion criteria
Refusal to consent

Date of first enrolment
01/07/2009

Date of final enrolment
30/12/2011

Locations

Countries of recruitment
Uganda

Study participating centre
Makerere University
Kampala
Uganda
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Sponsor information

Organisation

Save the Children (USA)

Sponsor details
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Sponsor type
Charity

Website
http://www.savechildren.org

ROR
https://ror.org/036jr6x18

Funder(s)

Funder type
Charity

Funder Name
Save the Children (USA) (ref: UG01_232)

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?
Protocol article	protocol	15/11/2012		Yes	No

Results article	results	31/03/2015	Yes	No
Results article	results	31/03/2015	Yes	No