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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
31/10/2009		[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

Protocol serial number

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

Study type(s)

Quality of life

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 careseeking 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(s)

- 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)

Key secondary outcome(s))

- 1. Neonatal mortality
- 2. Perinatal mortality

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

Healthy volunteers allowed

Age group

Adult

Sex

Female

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)

ROR

https://ror.org/036jr6x18

Funder(s)

Funder type

Charity

Funder Name

Results and Publications

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	31/03/2015	Yes	No
Results article	results	31/03/2015	Yes	No
Protocol article	protocol	15/11/2012	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes