ISRCTN16247511 https://doi.org/10.1186/ISRCTN16247511

Community-based perinatal and newborn care in rural Pakistan: a cluster randomised controlled trial

Submission date 09/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/02/2006	**Overall study status** Completed	
Last Edited 02/03/2011	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jose Martines

Contact details
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH 1211
martinesj@who.int

Additional identifiers

Protocol serial number
01006HNI

Study information

Scientific Title

Study objectives
The promotion of improved newborn care by first level health workers (traditional birth attendants, lady health workers and midwives) together with increased community participation in newborn care will lead to a substantial reduction in neonatal and perinatal mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received on the 21st June 2005.

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Newborn sepsis, birth asphyxia, pneumonia

Interventions
1. Improved newborn care by first level health workers (traditional birth attendants, lady health workers and midwives)
2. Increased community participation in newborn care

For further information please contact Dr Martines at the address listed below or the principal investigator:
Dr Zulfiqar Bhutta
Department of Paediatric and Child Health
Aga Khan University
Stadium Road
Karachi
P.O. Box 3500
Pakistan
Email: zulfiqar.bhutta@aku.edu

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Newborn mortality
2. Perinatal mortality

Key secondary outcome(s)

1. Early initiation of breastfeeding
2. Exclusive breastfeeding

Completion date
30/06/2008

Eligibility

Key inclusion criteria
All newborns in the study community are eligible for inclusion.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Refusal to participate.

Date of first enrolment
01/08/2002

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Pakistan

Switzerland

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO) (Switzerland)

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO) (Switzerland)

Funder Name
Saving Newborn Lives (SNL) (USA)

Funder Name
United Nations Children's Fund (UNICEF)

Funder Name
Government of Pakistan (Pakistan)

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	29/01/2011	Yes	No