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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Jose Martines

#### Contact details

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# 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.

# Study design

Cluster randomised controlled trial

# Primary study design

Interventional

# 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:

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# **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