

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

<b>Submission date</b> 09/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/03/2011	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Quality of life

## Participant information sheet

## 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 measure**

1. Newborn mortality
2. Perinatal mortality

**Secondary outcome measures**

1. Early initiation of breastfeeding
2. Exclusive breastfeeding

**Overall study start date**

01/08/2002

**Completion date**

30/06/2008

**Eligibility****Key inclusion criteria**

All newborns in the study community are eligible for inclusion.

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

36,000

**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)

## Sponsor details

20 Avenue Appia

Geneva-27

Switzerland

CH-1211

[martinesj@who.int](mailto:martinesj@who.int)

## Sponsor type

Research organisation

## Website

<http://www.who.int>

## 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

**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?
<a href="#">Results article</a>	results	29/01/2011		Yes	No