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Making birthing safe for women in Pakistan

Submission date	Recruitment status	[_] Prospectively registered
16/05/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/07/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2017	Pregnancy and Childbirth	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In Pakistan, deaths of mothers and newborns are still at a level considered high for the country. The Maternal, Neonatal and Child Health (MNCH) programme has been launched with five key strategic components. Improved availability and use of skilled birth attendants, and emergency obstetric and neonatal care through strengthened primary health care facilities are the two key approaches to making birthing safe. A nationwide network of about 100,000 lady health workers is already involved in antenatal and postnatal care of pregnant women. They also act as “gatekeepers” for the child birthing services. This gatekeeping role mainly includes counseling and referral for skill birth attendance and travel arrangements for emergency obstetric care (if required). The review of current arrangements and practices shows that the care delivery process needs improvement to include adequate information provision as well as informed decision making and planned action taking by pregnant women. The two interventions to be tested in this study are: enabling the pregnant women and families to plan and prepare for safe birth (i.e. address the delay in decision-making); and mobilizing the communities to arrange travel for emergency obstetric care (i.e. address the delay in timely access). The aim of this study is to assess whether these interventions increase the use of safe birthing services and reduces the newborn mortality (death) rate.

Who can participate?
Primary healthcare facilities in three selected districts of Punjab (Jhang, Chiniot and Khanewal)

What does the study involve?
Participating healthcare facilities are randomly allocated into three groups. Pregnant women in group 1 are given interventions to address decision delays plus access delays. Those in group 2 are given interventions to address decision delays only. Group 3 receive routine care. A total of 75,600 pregnancies in the three groups are followed up for their birthing practices and pregnancy outcomes.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Primary healthcare facilities in three selected districts of Punjab (Jhang, Chiniot and Khanewal) (Pakistan)

When is the study starting and how long is it expected to run for?
February 2011 to May 2013

Who is funding the study?
Research & Advocacy Fund (Pakistan)

Who is the main contact?
Dr Muhammad Amir Khan

Contact information

Type(s)
Scientific

Contact name
Dr Muhammad Amir Khan

Contact details
12, Street 48
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RAF/LG/DTL/18-6/20

Study information

Scientific Title
Making birthing safe for women in Pakistan a cluster randomized controlled trial

Study objectives
Structured planning for safe birthing and effective Emergency Obstetric & Newborn Care (EmONC) services and/or travel facilitation in Pakistan, facilitated mainly through female health workers will reduce the neonatal mortality rate

Ethics approval required
Old ethics approval format

Ethics approval(s)

National Bioethics Committee (NBC) Pakistan, 16/08/2010, ref: 4-87/10/NBC-39/RDC/487

Study design
Cluster randomized three arm controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

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, neonatal and child health

Interventions
1. Arm 1: structured planning for safe birthing/EmONC
2. Arm 2: structured planning for safe birthing/EmONC plus transport facilitation
3. Arm 3: no transport facilitation or structured birth planning-education for safe birthing /EmONC (current/routine practice)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Neonatal mortality rate (NMR)

Secondary outcome measures
Neonatal morbidity rates

Overall study start date
01/02/2011

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Elibility criteria for population is the availability of safe birthing and EmONC services (made available through the Maternal Newborn and Child Health (MNCH) Programme) and a functioning network of lady health workers (through the National Programme for Primary Health Care and Family Planning)
2. All pregnancies in the selected clusters will be eligible

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
75,600 total pregnancies will be recruited, 25,200 pregnancies in each of the three arms

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/02/2011

Date of final enrolment
31/05/2013

Locations

Countries of recruitment
Pakistan

Study participating centre
12, Street 48
Islamabad
Pakistan
44000

Sponsor information

Organisation
Research & Advocacy Fund (Pakistan)

Sponsor details

23A Street 8
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Sponsor type
Research council

Website
http://www.rafpakistan.org/

ROR
https://ror.org/05rf29967

Funder(s)

Funder type
Research council

Funder Name
Research & Advocacy Fund (RAF) Ref: RAF/LG/DTL/18-6/20

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	15/07/2012		Yes	No