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Community health and medical provision: impact on neonates

Submission date 07/02/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/03/2007	**Overall study status** Completed	
Last Edited 06/07/2017	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Version 1.0, 05/02/07

Study information

Scientific Title
Community Health And Medical Provision: Impact On Neonates (CHAMPION)

Acronym
CHAMPION

Study objectives
Neonatal mortality rates in India are high compared to other low income countries, and there is a wide variation of rates across regions. One area with a particularly high rate is Mahabubnagar District in the state of Andhra Pradesh, where neonatal mortality is estimated to be in the region of 4-9%. The area suffers from a vicious cycle of both poor supply of and small demand for health care services.

Neonatal mortality can be reduced through systemic changes to the provision and promotion of health care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the L.V. Prasad Eye Institute, Hyderabad, India, ref: LEC07002 - approval pending

Study design
Unblinded cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

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
Neonatal mortality

Interventions

Unblinded cluster-randomised controlled trial involving 464 villages, with the village as the unit of randomisation

A multi-level program: community health promotion and contracting out primary and secondary health services to non-public providers. The health promotion campaign will include a health education campaign, participatory discussion groups, training of village health workers and midwives, and improved coordination of antenatal services. These services will be provided for free to pregnant women and neonates in the intervention communities. The intervention group will also have subsidised access to primary and secondary pregnancy-related health care services at non-public health centres.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Neonatal mortality

Secondary outcome measures
1. Neonatal death
2. Neonatal morbidity
3. Maternal mortality and morbidity
4. Health service usage
5. Costs and several process
6. Knowledge outcomes

Overall study start date
01/09/2007

Completion date
01/01/2011

Eligibility

Key inclusion criteria
The trial site is the Nagarkurnool division of Mahabubnagar district in the Indian state of Andhra Pradesh. The trial will involve only those villages in the division with a population of less than 2,500 people. A woman is eligible for inclusion in the trial if she satisfies the following criteria: she is married, less than 50 years old, and resident in one of the 464 villages at the time of a baseline survey that is to be carried out immediately prior to randomization. Once the baseline survey has been carried out and the eligible women listed, the only permitted addition to the trial will be those women who marry into a trial village. Women will not be added or removed from the list as a result of either temporary or permanent migration from the village in which they are initially registered.

Only those children of eligible women whose estimated date of delivery at enumeration is at least six months after randomization will be included in the trial. As training and establishment of services in intervention villages will require time to be achieved, this lag in measurement is necessary to ensure exposure to the intervention.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
464 villages

Key exclusion criteria
Women and their children will be excluded from the trial if the woman in question is unmarried, if she is aged 50 or over at the time of the baseline survey or if she refuses to participate in the baseline survey.

Date of first enrolment
01/09/2007

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
England

India

United Kingdom

Study participating centre
Effective Intervention
London
United Kingdom
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Sponsor information

Organisation
Effective Intervention (UK)

Sponsor details

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Sponsor type
Charity

Website
http://www.effint.org/

ROR
https://ror.org/00a1wp308

Funder(s)

Funder type
Charity

Funder Name
Effective Intervention in the Centre for Economic Performance at the London School of Economics (UK registered charity no. 1111709) (UK)

Funder Name
The Naandi Foundation (India trust registration number 1745/98) (India)

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?
Results article	results	05/07/2017		Yes	No