ISRCTN35833344 https://doi.org/10.1186/ISRCTN35833344

Multiple micro-nutrient supplementation of low-birth-weight infants in Pakistan: a randomised controlled trial

Submission date 13/10/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/04/2006	**Overall study status** Completed	
Last Edited 19/10/2009	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Zulfiqar Ahmed Bhutta

Contact details
Department of Pediatrics
Aga Khan University
Stadium Road
Karachi
Pakistan
74800
+92 21 486 4721
zulfiqar.bhutta@aku.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9907

Study information

Scientific Title

Acronym
MICR

Study objectives
A six-month supplementation with a combination of vitamin A, iron, zinc, copper, folic acid and vitamin D will improve growth of infants

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethical Review Committee of Aga Khan University Karachi, Pakistan in September 2001 with the reference number 100-Ped/ERC-01

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Low-birth-weight infants

Interventions
The infants were exclusively breastfed and received the supplement or placebo daily for six months. The infants were followed up at home at mostly intervals by teams of research medical officers and community health nurses, up till 12 months of age.

Following informed written consent the newborn infants were randomised to the following treatment groups in a blinded fashion using randomisation codes in blocks of 20. The randomisation codes were kept at the Aga Khan University Pharmacy Department and were available on phone to the research teams.

Group A: received a one daily oral supplement providing moisture of iron, copper, zinc, vitamin A and D for six months along with the recommended daily allowance (RDA) of a standard multivitamin mixture (Surbex, Abbot) for six months
Group B: received a placebo daily and standard multivitamin moisture (Surbex, Abbott)

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamin A and D, iron, zinc, copper and folic acid

Primary outcome measure
1. Growth (weight gain and linear growth)
2. Morbidity rates (days ill with diarrhea and respiratory infections)

Secondary outcome measures
Neurodevelopmental outcome at 6 and 12 months. This will be objectively evaluated in a blinded fashion by a team comprising of a pediatric neurologist and fully trained child development expert.

Overall study start date
01/05/1999

Completion date
01/05/2002

Eligibility

Key inclusion criteria
Six to twelve month old infants identified after birth at tertiary care hospital

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
400 infants in each arm (two groups)

Key exclusion criteria
1. Children with major congenital or chronic disorders
2. Loss to follow up

Date of first enrolment
01/05/1999

Date of final enrolment
01/05/2002

Locations

Countries of recruitment
Pakistan

Study participating centre
Department of Pediatrics
Karachi
Pakistan
74800

Sponsor information

Organisation
Applied Research on Child Health Project (ARCH) (USA)

Sponsor details
Center for International Health
Boston University
School of Public Health
715 Albanay Street
710
Boston
United States of America
MA 02118
+1 617 414 1260
archcih@bu.edu

Sponsor type
Charity

Website
http://www.international-health.org/ARCH/

Funder(s)

Funder type

Research organisation

Funder Name
Applied Research on Child Health Project (ARCH) (USA)

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