

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/10/2009	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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United States of America

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+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