

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
Registration date 28/04/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 19/10/2009	Condition category Neonatal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Double-blind randomised placebo-controlled trial

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

Funder(s)

Funder type

Research organisation

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration