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Impact of zinc supplementation in low birth weight infants on severe morbidity and zinc status: a randomised controlled trial (India)

Submission date 08/02/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/02/2005	**Overall study status** Completed	
Last Edited 15/07/2021	**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
NCT00272142

Secondary identifying numbers

WHO/HNI04002

Study information

Scientific Title
Impact of zinc supplementation in low birth weight infants on severe morbidity and zinc status: a randomised controlled trial (India)

Study objectives
To determine the impact of daily oral supplementation of 1 Recommended Daily Allowance (RDA) of zinc in low birth weight infants on:
1. All causes hospitalisations, and
2. Illnesses requiring visit to health care providers

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the World Health Organization (WHO) Ethical Review Committee on the 26th October 2005.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Low Birth Weight (LBW)

Interventions
2000 infants in total: Infants in the intervention group will receive one Recommended Daily Allowance (RDA) of elemental zinc (5 mg elemental zinc per day in infants aged 14 days to 6 months and 10 mg per day for infants older than six months) daily for a period of one year compared to placebo (plain glucose) in the control group for a period of 12 months.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Zinc supplementation

Primary outcome measure
1. Hospitalisations, measured at three monthly intervals
2. Healthcare provider visits, measured at three monthly intervals
3. Diarrhoea and Acute Respiratory Infection (ARI) morbidity, measured at three monthly intervals
4. Mortality, death identified at regular home visits
5. Proportion of stunted and under weight children, measured at three monthly visits
6. Plasma zinc, copper and iron, measured at baseline and end of study

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/09/2004

Completion date
10/09/2005

Eligibility

Key inclusion criteria
1. Infants aged 14 to 28 days born after 37 weeks of gestation and weighing less than or equal to 2.5 kg at birth (less than 10th percentile of the National Center for Health Statistics [NCHS] median birth weight)
2. Either sex
3. Resides within 7 km of the hospital

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
2000

Total final enrolment
2052

Key exclusion criteria

1. Likely to leave the area of residence within six months of enrolment, i.e. visitors to the area, those that have already planned to visit their village, those definite that they are moving to another locality
2. Congenital malformations, congenital heart disease, metabolic disorders, renal diseases etc.
3. Non-consent for participation
4. Temporary exclusion criteria: illness requiring hospitalisation
5. Twins

Date of first enrolment
10/09/2004

Date of final enrolment
10/09/2005

Locations

Countries of recruitment
India

Switzerland

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO) (Switzerland)

Sponsor details
20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor type
Research organisation

Website
http://www.who.int

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
The Department of Child and Adolescent Health (CAH)/World Health Organization (WHO) (Switzerland)

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		01/08/2009	15/07/2021	Yes	No