ISRCTN85633178 https://doi.org/10.1186/ISRCTN85633178

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

| | | |
|---|---|---|
| **Submission date**<br>08/02/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>10/02/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>15/07/2021 | **Condition category**<br>Neonatal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Olivier Fontaine

**Contact details**
World Health Organization
20, Avenue Appia
Geneva-27
Switzerland
CH 1211
+41 22 791 2894
fontaineo@who.int

## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00272142

**Protocol serial number**
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

## Study type(s)
Quality of life

## 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(s)
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

### Key secondary outcome(s))
Not provided at time of registration

### 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

### Healthy volunteers allowed
No

### Age group
Neonate

### Sex
All

### 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)

### 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

### 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 |