

Establishing the optimal dose of therapeutic zinc supplementation for the treatment of acute diarrhoea in under five children - a dose response trial in a South Asian and a Sub-Saharan African setting

Background /Rationale

The Zinc Therapeutic Dosage Trial (ZTDT) seeks to answer the question whether lower dosages of zinc will increase caretakers' willingness to utilize zinc as part of standard diarrhoea case management. Zinc as a heavy metal is not very palatable and is associated with excess vomiting. Current WHO technical recommendations require 20 mg of zinc. We are testing whether lower dosages (10 mg and 5 mg) compared to the standard dosage (20 mg) are as clinically efficacious (same reduction in duration of diarrhoea) and have a lower side effect profile (less acute vomiting after treatment).

Study Questions & Design

In a three arm randomized and blinded clinical trial we propose to determine the optimal dose (20 mg or 10 mg or 5 mg) of therapeutic zinc supplement for the treatment of children aged 6 - 59 months with acute diarrhoea. We will enrol 4500 study subjects (1500 subjects per arm).

Programmatic Implications

A lower dose (5 or 10 mg) of zinc, if clinically as efficacious as the current dosage (20 mg) and with a less frequent side effect profile, may lead to greater utilization of zinc in diarrhoea standard case management. As zinc has been shown to reduce severity and duration of diarrhoea this has major programmatic and health implications.

Locations & Collaborators

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Data Collection

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