

# Randomised trial of treatment of chronic suppurative otitis media (CSOM) in Kenyan children

<b>Submission date</b> 25/11/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/05/2022	<b>Condition category</b> Ear, Nose and Throat	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Treatment of chronic suppurative otitis media (CSOM) in Kenyan children: a double blind, two-group comparative randomised placebo controlled trial

## Acronym

COMIGS

## Study objectives

The addition of oral zinc sulphate supplements (20 mg elemental zinc/day) to current best treatment (aural antibiotics instilled after ear cleaning) is more effective than current best treatment alone in time to resolution of chronic suppurative otitis media (CSOM) in children.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Pending as of 25/11/2008:

1. University of Nairobi Ethics Committee: submitted 18/11/2008
2. Liverpool School of Tropical Medicine Ethics Committee: submitted 20/11/2008

## Study design

Double blind, two-group comparative randomised placebo controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Chronic suppurative otitis media (CSOM)

## Interventions

1. Six weeks of weekly oral zinc sulphate supplement (20 mg) together with 10 days of aural ciprofloxacin 0.3% ear drops
2. Six weeks of weekly oral placebo together with 10 days of aural ciprofloxacin 0.3% ear drops

## Intervention Type

Supplement

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Zinc sulphate supplement, ciprofloxacin

**Primary outcome measure**

Healing of the tympanic membrane at 42 days with no evidence of perforation on otoscopy, tympanometry or the Rinne Test has changed from negative to positive.

**Secondary outcome measures**

1. Resolution of aural discharge
2. Any change of 10 decibels or more over the speech frequencies
3. Safety profiles of the two treatments

Children will be reviewed at 6, 10 and 16 weeks.

**Overall study start date**

01/02/2009

**Completion date**

01/02/2010

## **Eligibility**

**Key inclusion criteria**

1. Aged 5 years or older, either sex
2. Presence of purulent aural discharge for 14 days or longer
3. Presense of pus in the external ear canal on otoscopy
4. Perforation of the tympanic membrane

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

5 Years

**Sex**

Both

**Target number of participants**

432 school age children (5 years and older)

**Key exclusion criteria**

1. Treated for ear infection or received antibiotics for any other disease in the previous 2 weeks
2. Other ear problems, e.g. pre-existing ear disease or anatomical abnormalities
3. Foreign body or ear wax that is not able to be removed
4. Known allergy to study drugs

**Date of first enrolment**

01/02/2009

**Date of final enrolment**

01/02/2010

## Locations

**Countries of recruitment**

England

Kenya

United Kingdom

**Study participating centre**

**Liverpool School of Tropical Medicine**

Liverpool

United Kingdom

L3 5QA

## Sponsor information

**Organisation**

Liverpool School of Tropical Medicine (UK)

**Sponsor details**

Pembroke Place

Liverpool

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macken34@liv.ac.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.liv.ac.uk/lstm>

**ROR**

<https://ror.org/03svjbs84>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Thrasher Research Fund (USA)

**Alternative Name(s)**

TRF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United States of America

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration