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

Submission date 25/11/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/12/2008	**Overall study status** Completed	
Last Edited 16/05/2022	**Condition category** Ear, Nose and Throat	

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-exiting 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
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Sponsor information

Organisation
Liverpool School of Tropical Medicine (UK)

Sponsor details
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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