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To determine if the addition of weekly zinc and weekly zinc plus vitamin A to routine tuberculosis (TB) treatment improves the outcome of the treatment in Nigeria

Submission date
24/06/2009

Registration date
24/07/2009

Last Edited
23/10/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Lovett Lawson

Contact details
Zankli Medical Centre
1021, Shehu Yaradua Way
Abuja
Nigeria
P.O.Box 7745
+234 (0)803 701 2487
lovettlawson@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Diagnosis of tuberculosis and the role of micronutrients in the treatment of pulmonary tuberculosis (PTB) in Nigeria: a double-blinded, placebo-controlled, multicentre, supplementation clinical trial

Study objectives
To assess the efficacy of weekly zinc and weekly zinc plus vitamin A as an adjunct for the treatment of patients with tuberculosis (TB).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Liverpool School of Tropical Medicine Research Ethics Committee approved on the 25th July 2003 (ref: 03.33)
2. Ministry of Federal Capital Territory, Health and Social Services Department, Nigeria approved on the 23rd June 2003 and 16th July 2003 (ref: MFCT/GEN/24/VOL1)

Study design
Double-blinded block randomised placebo-controlled multicentre supplementation clinical 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
Tuberculosis

Interventions
Patients were randomised in blocks to receive:
1. Anti-TB routine treatment plus 90 mg elementary zinc weekly (as zinc sulphate in a lactose matrix in form of a tablet) plus a placebo that looked identical to vitamin A
2. Anti-TB treatment plus 90 mg elementary zinc weekly plus 1500 retinol (equivalent to 5000 IU

of vitamin A as retinyl acetate, in a capsular form)
3. Anti-TB treatment plus weekly placebos that were similar to zinc tablets and vitamin A capsules

All capsules and tablets were prepared and sent from the Liverpool School of Tropical Medicine. The tablets and the capsules were indistinguishable to both researchers and patients.

Total duration of treatment was 8 months and the total duration of the follow-up for all arms was 6 months.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Zinc, vitamin A supplementation

Primary outcome measure
1. To determine the time to sputum clearance of bacilli (proportion of TB bacilli cleared from sputum at enrolment, 2nd and 6th month, using smear microscopy in the three groups)
2. To determine the resolution of lesion areas in chest x-rays in the three groups at enrolment, 2nd and 6th month

Secondary outcome measures
To look at the clinical and laboratory differences between the three groups at enrolment, 2nd and 6th month.

Overall study start date
01/09/2003

Completion date
30/06/2005

Eligibility

Key inclusion criteria
1. Willingness to take part in the study
2. Newly diagnosed as having active PTB as per the World Health Organization (WHO) definition of smear positive TB
3. Aged 15 years and above, either sex
4. Should not have a history of anti-TB treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
350

Total final enrolment
350

Key exclusion criteria
1. Moderate to severe surgery during the previous month
2. History of diabetes mellitus or severe cardiovascular, liver or renal diease
3. Previous treatment for TB
4. Taking corticosteroids, zinc or vitamin A supplementation during the previous month
5. Pregnant, lactating or taking oral contraceptives
6. Patient could not attend follow up visits regularly

Date of first enrolment
01/09/2003

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Nigeria

Study participating centre
Zankli Medical Centre
Abuja
Nigeria
P.O.Box 7745

Sponsor information

Organisation
Zankli Medical Centre (Nigeria)

Sponsor details
1021, Shehu Yaradua Way
Abuja
Nigeria

P.O.Box 7745
+234 (0)9 670 7273 4
zankli@hotmail.com

Sponsor type
Hospital/treatment centre

Website
http://www.zankli.com

ROR
https://ror.org/02msz7b29

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Zankli Medical Centre (Nigeria)

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	results	01/12/2010	23/10/2020	Yes	No