

# 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

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

24/07/2009

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

23/10/2020

**Condition category**

Infections and Infestations

☐ Individual participant data

**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

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 disease
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**

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**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?
<a href="#">Results article</a>	results	01/12/2010	23/10/2020	Yes	No