

# Improving tuberculosis treatment by high-energy biscuits in Mwanza, Tanzania

**Submission date**  
31/08/2010

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
22/09/2010

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
15/05/2014

**Condition category**  
Infections and Infestations

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Nyagosya Range

### Contact details

NIMR Muhimbili

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Tanzania

N/A

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

**Scientific Title**

Improving Efficacy and Safety of TB and HIV Treatment by Nutritional Supplementation in Mwanza, Tanzania: A prospective, randomised, open labelled study

**Acronym**

TB-PK study

**Study objectives**

A defined, high energy, vitamin and mineral containing nutritional supplement to undernourished tuberculosis (TB) patients during the first two months of intensive treatment will improve drug absorption, ameliorate adverse effects and fasten recovery of lean body mass.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The local medical ethics committee approved on the 1st of June 2010 (ref: NIMR/HQ/R.8a/Vol.IX /953)

**Study design**

Prospective open labelled randomised controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Is prepared in English and in local language. Will in addition be orally presented to participants by study nurses.

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

Tuberculosis with and without HIV co-infection

**Interventions**

Patients will be randomised to either:

1. Intervention group:

Five high energy biscuits containing 1000 kcal plus vitamins, minerals zinc and selenium every day during the intensive phase of the anti TB treatment as part of the Directly Observed Treatment (DOT) regimen.

2. Control group: Standard care

**Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Increase in TB drug exposure (AUC) during the first two months in the group receiving intervention compared to the group receiving standard care.

## **Secondary outcome measures**

1. Improved immune recovery (CD4 increase) and decline in HIV RNA load in the intervention group
2. Improved and faster increase in lean body mass and physical strength
3. Less reporting of adverse effects

## **Overall study start date**

01/09/2010

## **Completion date**

31/08/2011

# **Eligibility**

## **Key inclusion criteria**

1. Sputum smear positive TB patients
2. > 15 years old

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

100

## **Key exclusion criteria**

1. Pregnant women
2. Age < 15 years
3. Non-residency of study area
4. Terminal illness (unlikely to survive > 48 hours)
5. Receiving antiretroviral therapy
6. Not willing to participate

## **Date of first enrolment**

01/09/2010

**Date of final enrolment**

31/08/2011

**Locations****Countries of recruitment**

Tanzania

**Study participating centre**

NIMR Muhimbili

Dar es Salaam

Tanzania

N/A

**Sponsor information****Organisation**

University of Copenhagen (Denmark)

**Sponsor details**

c/o Aase Bengaard Andersen

Faculty of health Sciences

Department of Infectious Diseases

Rigshospitalet

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**Sponsor type**

University/education

**ROR**

<https://ror.org/035b05819>

**Funder(s)****Funder type**

Government

**Funder Name**

## 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	01/06/2014		Yes	No