

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

<b>Submission date</b> 31/08/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/05/2014	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

## 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)

### **Primary study design**

Interventional

### **Study design**

Prospective open labelled randomised controlled study

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

### **Completion date**

31/08/2011

# Eligibility

## Key inclusion criteria

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

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## 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)

## ROR

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

## Funder(s)

### Funder type

Government

### Funder Name

Danish Ministry of Foreign Affairs (Denmark) - Danish International Development Agency (Danida) grant (ref: 09-026RH)

## Results and Publications

### 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