

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

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Contact details

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Tanzania

N/A

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Additional identifiers

Protocol serial number

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

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?
Results article	results	01/06/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes