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

Submission date	Recruitment status	[_] Prospectively registered
31/08/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/09/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/05/2014	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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