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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

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
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Sponsor type
University/education

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

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?
Results article	results	01/06/2014		Yes	No