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Nutrition and wasting in tuberculosis (TB): Can nutritional supplementation in TB patients improve body weight gain, body composition and treatment outcome?

Submission date
30/04/2007

Recruitment status
No longer recruiting

Registration date
30/08/2007

Overall study status
Completed

Last Edited
30/08/2007

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
WV93-411

Study information

Scientific Title

Acronym
TBGIZI ("GIZI" means "nutrition" in Indonesian)

Study objectives
Th hypothesis is that supplementation of TB patients with macro- and micronutrients patients during the first 2 months of treatment increases body weight gain, as compared to TB patients on standard TB treatment. Secondary hypothses include that above supplementation will increase the production of pro-inflammatory cytokines as measured by ex-vivo whole blood stimulation assay and that lean body mass increases more in patients receiving micro- and macronutrient supplementation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Ethical Review Board of Hasan Sadikin University, University of Padjajaran, Bandung, Indonesia, approved in August 2006
2. The Ethical Advisory Board, Radboud University Nijmegen, The Netherlands, approved on 16 Feb 2007

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Tuberculosis / nutritional status and wasting / nutrition and public health

Interventions
Newly diagnosed TB patients who fullfil the eligiblity criteria will be randomly allocated according to a previously made random list (randomization in blocks of 4) to either standard treatment + nutritional supplementation (75 patients) or standard treatment only (75 patients). Patients allocated to the nutritional supplementation group will receive 3 biscuits per day for 2 months, containg macro- and micronutriets in addition to their standard TB treatment. These 3 biscuits will provide approximately 450 KCal of energy (or approximately 20% of the daily energy requirements), as well as a wide range of minerals and vitamins, in a doses of approximately half the Daily Required Intakes (DRIs), and NOT containing iron. Patients will be followed up according to standard clinical practice by the health services until the end of the intensive TB drug treatment phase (2 months).

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
Body weight gain and body composition between start of TB treatment and end of the active phase of treatment (2 months later)

Key secondary outcome(s))
The following will be assessed at baseline and 2 months:
1. Micronutrient status
2. Production of inflammatory cytokines

Completion date
01/01/2008

Eligibility

Key inclusion criteria
Subjects must meet all of the following inclusion criteria to be eligible for participation in this study:
1. Patients with Ziehl-Neelsen (ZN) staining - positive pulmonary TB
2. Patients starting, or started <2 weeks ago, with the intensive phase of TB treatment
3. Subject is >18 years of age
4. Willing to participate in the study, and signing the informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
No informed consent.

Date of first enrolment
15/05/2007

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Indonesia

Study participating centre
Dept. of Internal Medicine
Bandung
Indonesia
40161

Sponsor information

Organisation
NWO/WOTRO - Netherlands Organisation for Scientific Research (The Netherlands)

ROR
https://ror.org/04jsz6e67

Funder(s)

Funder type
Government

Funder Name
NWO/WOTRO - Netherlands Organisation for Scientific Research (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration