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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/08/2007	**Overall study status** Completed	
Last Edited 30/08/2007	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Frank Wieringa

Contact details
Dept. of Internal Medicine
Hasan Sadikin Hospital
Jl. Pasir Kaliki 191
Bandung
Indonesia
40161
+62 22 2038 986
wieringa@tiscali.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
The following will be assessed at baseline and 2 months:
1. Micronutrient status
2. Production of inflammatory cytokines

Overall study start date
15/05/2007

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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
150

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)

Sponsor details
Anna van Saksenlaan 51
The Hague
Netherlands
2593 HW
+31 (0)70 3440763
WOTRO@nwo.nl

Sponsor type
Government

Website

http://www.nwo.nl/nwohome.nsf/pages/NWOA_6UB9S8

ROR
https://ror.org/04jsz6e67

Funder(s)

Funder type
Government

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

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