

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	<input type="checkbox"/> Prospectively registered
Registration date 30/08/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/08/2007	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

The hypothesis is that supplementation of TB patients with macro- and micronutrients during the first 2 months of treatment increases body weight gain, as compared to TB patients on standard TB treatment. Secondary hypotheses 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 fulfil the eligibility 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, containing macro- and micronutrients 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

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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