ISRCTN12506117 https://doi.org/10.1186/ISRCTN12506117

Malnutrition and diabetes in tuberculosis treatment programs in the Philippines

Submission date
15/05/2017

Recruitment status
No longer recruiting

Registration date
19/05/2017

Overall study status
Completed

Last Edited
23/03/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tuberculosis (TB) is a bacterial infection that affects mainly the lungs and is spread through tiny droplets from coughs or sneezes. Wasting and malnutrition are common in patients infected with TB and are associated with mortality (death) and adverse outcomes. Under-nutrition is a risk factor and complication of active TB disease. Diabetes mellitus (a lifelong condition that causes a person's blood sugar level to become too high) is another risk factor for TB. Patients with diabetes are three times more likely to develop TB, while TB causes glucose (sugar) intolerance and can worsen glycemic (blood sugar) control among diabetics. However, there is little known about the prevalence of wasting and diabetes among TB outpatients in the Philippines. It is likely that nutritional programmes may improve TB outcomes for malnourished patients however there are no international or Filipino guidelines for nutritional support during TB treatment. There is a need for data on the prevalence of malnutrition, TB treatment outcome related to wasting and on malnutrition and diabetes prevalence in order to inform more research. The aim of this study is to evaluate the prevalence of wasting and diabetes among TB outpatients in the Philippines in order to improve the nutrition outcomes for malnourished patients and create guidelines for nutritional support during TB treatment.

Who can participate?
Adults aged 18 and older who are registered TB DOTS patients at certain clinics.

What does the study involve?
Participants are randomly invited to join the study while they attend a health clinic for treatment for their TB or other co-morbidities (illnesses). During this visit, participants complete questionnaires on health and social factors including TB diagnosis, treatment, compliance to medications, side effects of medications, quality of life, cost of treatment, food security and appetite. Participants are also measured for their weight, height, handgrip strength, mid upper arm circumference, waist/hip circumference. Participants also provide blood samples from fingerpricks to determine if they have diabetes or HIV.

What are the possible benefits and risks of participating?
Participants may benefit from being screened for diabetes. There are no notable risks with participating however participants may experience discomfort when they provide blood samples through the fingerprick test.

Where is the study run from?
This study is being run from three health centres in Manila and two health centres in Negros Occidental (Philippines).

When is the study starting and how long is it expected to run for?
September 2016 to October 2017

Who is funding the study?
Nagasaki University (Japan)

Who is the main contact?
Dr Sharon Cox
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Malnutrition and Tuberculosis in the Philippines: prevalence of undernutrition and diabetes in TB control programmes

Acronym
Mal-TB DOTS

Study objectives
The aim of this study is to evaluate the prevalence of wasting and diabetes among TB outpatients in the Philippines in order to improve the nutrition outcomes for malnourished patients and create guidelines for nutritional support during TB treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. National Ethics Committee - Philippine Council for Health Research and Development, 17/01/2017, ref: NEC code 2016-021-Cox-MalnutritionandTuberculosis
2. London School of Hygiene and Tropical Medicine, 20/03/2017, ref 11995
3. San Lazaro Hospital Research Ethics and Review Unit, 23/02/2017

Study design
Observational cross sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Tuberculosis, malnutrition, diabetes

Interventions
In this cross-sectional study, participants are randomly sampled as to when they are surveyed for data collection. This could be during their first week of TB treatment or their final week of treatment depending on when they are identified through the random sampling approach. The participants is invited to the study during presentation to the TBDOTS clinical or their local Barangay Health Station to obtain their medicine (or once tracked for those patients not regularly visiting the clinics) and once consent is obtained all study investigations and questionnaires are completed during that visit. There is no follow-up of patients.

Study investigations to be completed during the visit include questionnaires on health and social factors including TB diagnosis, treatment, compliance to medications, side effects of medications, quality of life, economic impact of TB on the participant, food security status, and appetite/intake data. Anthropometric data (weight, height, handgrip strength, mid upper arm circumference, waist/hip circumference) are measured at time of enrollment to the study. Fingerprick bloods samples are used to determine diabetes status (HbA1c), anemia (Hb), inflammation (CRP) and HIV status (if additional consent provided) at the time of enrollment.

Intervention Type
Other

Primary outcome measure
1. Prevalence of clinical wasting (BMI <17.0 kg/m2) is measured using the participants' weight and height at time of study enrollment
2. Prevalence of diabetes is measured using the Alere Afinion point of care test for HbA1c (diabetes defined as >6.5%) through a blood prick test or previous diagnosis at time of study enrollment

Secondary outcome measures
1. Factors associated with malnutrition (age, sex, region, duration of treatment, programme compliance, household food security and appetite) are measured using patient treatment cards at time of study enrollment
2. Prevalence of drug related side effects are measured using patient interview at time of study enrollment and one month
3. Handgrip strength measured using a strain-gauge based isometric Jamar Hand Dynamometer at time of study enrollment
4. BMI is measured using participants weight and height at time of study enrollment
5. Mid-upper arm circumference is measured using SECA measuring tape at time of study enrollment
6. Diabetes management is measured using patient interview at time of study enrollment
7. Anaemia is measured using hemoglobin value (obtained using Hemocue 301+ point of care

test) at time of study enrollment
8. Quality of life is measured using the WHO Quality of Life BREF survey at time of study enrollment
9. Patient related compliance (in the last week) is measured using interviews and document compliance through patient treatment cards at time of study enrollment

Overall study start date
30/09/2016

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. All registered TB DOTS patients at preselected clinics. This includes those with MDR TB, co-infection with HIV, and those with pre-existing diabetes or other co-morbidities.
2. Aged 18 and older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
n=750

Total final enrolment
637

Key exclusion criteria
Pregnant women.

Date of first enrolment
01/05/2017

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
Philippines

Study participating centre
San Lazaro Hospital
Manila
Philippines
1003

Study participating centre
Pedro Gil Health Center
Manila
Philippines
1017

Study participating centre
San Nicolas Health Center
Manila
Philippines
1002

Study participating centre
Bago City Health Center
Negros Occidental
Philippines
6101

Study participating centre
Valladolid Health Center
Negros Occidental
Philippines
6103

Sponsor information

Organisation
Nagasaki University

Sponsor details

Graduate School of Tropical Medicine and Global Health
1-12-4 Sakamoto
Nagasaki
Japan
852-8523

Sponsor type
University/education

Website
http://www.tmgh.nagasaki-u.ac.jp/

ROR
https://ror.org/058h74p94

Funder(s)

Funder type
University/education

Funder Name
Nagasaki University

Results and Publications

Publication and dissemination plan
Results to be shared with the Department of Health. Planned publications in high-impact peer reviewed journals.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository London School of Hygiene and Tropical Medicine server at https://maltbdots.odk.lshtm.ac.uk with only investigators having access to the data. Anonymized data will be stored in a repository after study completion and will be shared with interested parties upon reasonable request to Dr. Sharon Cox. Participant consent was obtained to store anonymized data in repository for period of 10 years after study completion.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	01/07/2020	23/03/2021	Yes	No
Results article	05/03/2020	23/03/2021	Yes	No