

The Food Incentives for Tuberculosis Treatment Compliance study in Dili, East Timor (FITTCET)

Submission date 12/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 25/11/2005	Overall study status Completed	☐ Protocol
Last Edited 28/10/2009	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00192556

Protocol serial number
A30746

Study information

Scientific Title

Acronym

FITTCET

Study objectives

Food incentives are an achievable, effective method of encouraging full adherence to Directly Observed Treatment-Short Course Programme (DOTS) and thus improved treatment outcomes in Dili, Timor-Leste.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Full ethics approval received on the 17th March 2005.

Primary study design

Interventional

Study design

Randomised trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Tuberculosis

Interventions

Patients enrolled will be randomised to receive either the food intervention or nutritional advice and followed for duration of treatment (eight months)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The proportion of patients who successfully complete the eight month course of TB treatment and achieve cure in each group (treatment success) and the proportion of patients who do not complete treatment or have persistent disease (treatment failure).

Key secondary outcome(s)

1. The proportion of clinic visits compared with expected, measured weekly for first 2 months then monthly for next 6 months
2. Response to treatment measures:
 - 2.1. Symptoms (cough, sputum, fever), measured at 4, 8, 24 and 32 weeks
 - 2.2. Changes in weight and Body Mass Index (BMI), measured at 4, 8, 24 and 32 weeks
 - 2.3. Sputum clearance, measured at at 8 weeks
 - 2.4. Nutritional markers, measured at 4, 8, 24 and 32 weeks

Completion date

30/06/2006

Eligibility

Key inclusion criteria

Adult Tuberculosis (TB) patients diagnosed at one of the participating clinics during the study period will be eligible for enrolment if they are:

1. 18 years of age or older
2. Diagnosed to have tuberculosis (sputum smear positive or smear negative or extrapulmonary TB) using the standard National Tuberculosis Programme (NTP) definition for this diagnosis
3. Have never received more than one month of anti-tuberculosis treatment in the past
4. Not pregnant
5. Voluntarily accept to be involved in this study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Does not comply with inclusion criteria.

Date of first enrolment

01/04/2005

Date of final enrolment

30/06/2006

Locations

Countries of recruitment

Switzerland

Timor-Leste

Study participating centre

20, Avenue Appia
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation

UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Other

Funder Name

United Nations Children's Fund (UNICEF)

Funder Name

United Nations Development Programme (UNDP)

Funder Name

World Bank

Funder Name

World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

Results and Publications

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	26/10/2009		Yes	No