

INHIBIT TB - Assessment of household isoniazid preventive therapy (IPT) and point-of-care CD4 testing in a tuberculosis household contact tracing program within South Africa

Submission date 12/07/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/07/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/01/2019	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Contact tracing for tuberculosis (TB) involves visiting the home of TB patients who agree, in order to screen other household members for HIV and TB. Those found to have previously undiagnosed HIV are then referred for a CD4 count (that measures the level of a substance called CD4 in the blood) to decide whether or not they need antiretroviral therapy (drug therapy) and for access to preventive medication including isoniazid and co-trimoxazole. We want to know whether finding out the CD4 count instantly using a point-of-care machine in the household increases the chance that people newly diagnosed with HIV attend a clinic for care. We also want to know whether provision of isoniazid to the household will increase usage and completion of this important preventive therapy that reduces the risk of TB.

Who can participate?

Newly diagnosed adult TB patients in two districts of South Africa and their household members.

What does the study involve?

TB patients will be told about the study in the TB clinic and if they are eligible and consent, their household will be recruited to the study and randomly allocated to one of three groups: A, B and C. The household will then be visited and consenting household members screened for TB and HIV. All households will then be re-visited three and six months later to find out whether care was sought and if so, from where. Those diagnosed as HIV infected in households allocated to group B will also receive an immediate CD4 count. In addition, those in group C will be able to receive a course of either co-trimoxazole (if their CD4 count is <350) or isoniazid (CD4 count >350) monthly in their homes if they consent. Group A receives standard care.

What are the possible benefits and risks of participating?

All participating household members will be screened for TB and HIV, increasing their chances of receiving important care. Those diagnosed as HIV infected in households allocated to groups B or C will also receive additional treatment designed to improve their care. The main risk of

participating is possible new knowledge of HIV or TB status, which may be psychologically distressing for participants.

Where is the study run from?

The Aurum Institute in Johannesburg, South Africa, in collaboration with the London School of Hygiene and Tropical Medicine, UK.

When is study starting and how long is it expected to run for?

The study has started recruiting in 2013 and will continue until early 2014. Follow-up will continue for another six months after this.

Who is funding the study?

Sanofi-Aventis, South Africa.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

INHIBIT TB - AUR2-7-115

Study information

Scientific Title

Assessment of household IPT and point-of-care CD4 testing in a tuberculosis household contact tracing program within South Africa: a cluster randomized trial

Acronym

INHIBIT TB

Study objectives

1. By introducing a rapid point of care (POC) CD4, the median time from enrollment to antiretroviral therapy (ART) initiation would be reduced primarily because of a reduction in the median time taken to complete CD4 staging.
2. IPT would work well in households that are TB contact traced because household contacts are likely to be healthier and thus eligible for IPT, they would also not need to visit the clinic to obtain IPT, thus limiting their exposure to infectious TB patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of the Witwatersrand, Human Research Ethics Committee: Ref number: M120493

Study design

Stratified cluster randomized trial with the randomization occurring at household level

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Tuberculosis (TB)

Interventions

We will be evaluating three arms of care.

1. A standard of care (SOC) arm where a TB symptom screening is administered to consenting participants. Participants with any TB symptom will be asked to provide sputum for laboratory testing. Participants with TB positive results will be contacted. Contacts less than 5 years will be referred for exclusion of active TB and management as per South African (SA) guidelines.
2. The second arm is similar to the SOC arm with the addition of a rapid point-of-care (POC) CD4 test for patients who test HIV positive.
3. The third arm which provides SOC, POC CD4 and either cotrimoxazole (CMX) for 3 months if $CD4 < 350$ or isoniazid preventative therapy (IPT) if $CD4 \geq 350$ to participants with no TB symptoms.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cotrimoxazole, Isoniazid

Primary outcome measure

Primary objectives: To compare primary outcomes by arm

1. To determine the effect of point of care CD4 on entry into HIV care for those who are diagnosed HIV positive in the household intervention, as measured by self-report at the three month visit.
2. To determine the effect of providing household IPT on uptake and completion of IPT, as measured at nine months by clinic records for Arm B and by our study pharmacy records for Arm C.

Secondary outcome measures

Secondary objectives:

1. To determine effect of point of care CD4 on uptake of HIV testing, as measured by uptake of HIV testing at the baseline visit.
2. To determine the effect of providing cotrimoxazole in households on entry into care, as measured by self-report at the three month visit.
3. To assess TB incidence 6 months after initial home visit, as measured by self-report at the six month visit.

Overall study start date

01/06/2012

Completion date

01/07/2014

Eligibility**Key inclusion criteria**

Index patient Inclusion Criteria:

1. Age over 18 years
2. Sputum smear-positive, culture positive or Xpert MTB/RIF positive
3. Started on TB treatment within the past 3 months

4. Index patient Exclusion Criteria:

- 4.1. Live alone

Household contact inclusion criteria:

1. Any individuals who have been in contact with the index patient and generally sleep and eat in the same household

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

11500

Key exclusion criteria

Household contact exclusion criteria

1. Children under 5 years will not be part of the randomization into the intervention but will be offered standard of care; consent will be asked for record review and follow up
2. Declines to participate and/or refusal to sign informed consent
3. Not available for interview after 3 visits to the household

Date of first enrolment

01/06/2012

Date of final enrolment

01/07/2014

Locations

Countries of recruitment

South Africa

Study participating centre

The Aurum Institute

Johannesburg

South Africa

2193

Sponsor information

Organisation

Sanofi Aventis South Africa (Pty) Ltd (South Africa)

Sponsor details

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Midrand

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Sanofi Aventis South Africa (Pty) Ltd, South Africa

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/03/2018	24/01/2019	Yes	No