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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

Registration date
26/07/2013

Last Edited
24/01/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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 reudced 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 Commitee: Ref number: M120493

Primary study design
Interventional

Study design
Stratified cluster randomized trial with the randomization occurring at household level

Study type(s)
Prevention

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 ≥350 to participants with no TB symptoms.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cotrimoxazole, Isoniazid

Primary outcome(s)
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.

Key secondary outcome(s)
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.

Completion date
01/07/2014

Eligibility

Key inclusion criteria
Index patient Inclusion Criteria:
1. Age over18 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

Funder(s)

Funder type
Industry

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

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	02/03/2018	24/01/2019	Yes	No