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Evaluation of resources to promote human immunodeficiency virus (HIV) testing in tuberculosis (TB) clinics

Submission date	Recruitment status	[_] Prospectively registered
28/09/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/07/2013	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Evaluation of information resources developed for 'human immunodeficiency virus (HIV) testing in tuberculosis (TB) clinics': a cluster randomised controlled step-wedged study

Acronym
The NKS TB-HIV Evaluation Study

Study objectives
The aim of this project is evaluate the implementation of recommendations from the British Human Immunodeficiency Virus (HIV) Association (BHIVA) guidelines on universal "opt-out" HIV testing for all individuals attending tuberculosis (TB) clinics and the value of information resources to support this. The guidelines recommends that all patients in TB clinics should be offered and recommended a HIV test irrespective of their age, and offer of the test is not based on an individual's risk factors.

The information material being evaluated in this study has been produced by a working group with representatives from Health Protection Agency (HPA), Primary Care Trusts, Chest Clinics, HIV services and voluntary organisations. The materials include information z-cards for patients, flip charts and leaflets for healthcare staff working in TB clinics. All these materials would be provided to the chest clinics free of charge.

To evaluate effectiveness of these leaflets we need to collect some information from the clinics over a 6-month period (August - January 2010). The data collection would include: London TB Register number, patients' initials and date of birth (DOB) (to check against LTBR number), and if HIV testing was offered and accepted with the date of test.

The material will be introduced to the clinics gradually and in a stepwise manner over 6 months. The order of allocation of clinics will be determined by computer generated random numbers. Clinics will receive resources at the allocated time over the next 6 months, this could be any time during the 6-month period of the evaluation project. However, we will collect the HIV testing data from all the clinics throughout this 6-month period to compare uptake rates before and after introduction of the leaflets.

Ethics approval required
Old ethics approval format

Ethics approval(s)
A formal enquiry was sent to the Camden and Islington Community Local Research Ethics Committee produced for this project. Application was submitted on the 24th March 2009 and a reply was received on the 23rd April 2009 confirming that this study is an evaluation of a health service and therefore does not require full ethical review.

Study design
Multicentre cluster randomised controlled step-wedged trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Tuberculosis, human immunodeficiency virus (HIV)

Interventions

Intervention:
Information resources developed to recommend and raise awareness on universal HIV testing in TB clinics include a z-card for patients, information leaflet for nurses and healthcare workers, a training session for health care staff and a table top information display (flip chart). These materials together with the introduction of a policy of opt-out testing will be the intervention.

Randomisation and allocation:
This will involve a sequential roll out of an intervention to TB clinics over a period of six months. A pair of clinics will be allocated to the intervention each month. By the end of the study all participating TB clinics would have received the intervention. The order in which the intervention is delivered will be determined using a computer generated random sequence. The unit of allocation is the TB clinic.

Masking:
Participants will not be blinded, however, the persons analysing the study will be blinded.

Data collection:
All participating clinics will provide data on uptake over the entire study period (before and after the introduction of the intervention). Data on the characteristics of clinics and annonymised information on patients/staff will be collected.

As this is a "step-wedged trial" the control group are all the clinics before implementing the 'opt out policy and intervention of resources'. Therefore the control group changes over the study period. The total duration of the trial is 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Ratio of uptake of HIV testing before (control arm) and after intervention. Reasons for refusing to accept the offer of HIV test will be analysed. Measured on the 30th of every month until March 2010.

Key secondary outcome(s))
Cost effectiveness, measured at the end of the trial

Completion date
10/04/2010

Eligibility

Key inclusion criteria
TB clinics in London and all TB patients (irrespective of their age and gender) attending these clinics within the time-frame.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Individuals who do not consent
2. Patients attending the TB clinic but not diagnosed with TB

Date of first enrolment
10/10/2009

Date of final enrolment
10/04/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
61 Colindale Avenue
London
United Kingdom
NW9 5EQ

Sponsor information

Organisation
Health Protection Agency (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name
Health Protection Agency (UK)

Alternative Name(s)
HPA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/03/2013		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes