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Trial of human immunodeficiency virus (HIV) screening in Primary Care

Submission date	Recruitment status	[_] Prospectively registered
17/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/10/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ihse.qmul.ac.uk/chsgppc/RHIVA%202/index.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
006808QM

Study information

Scientific Title
Effectiveness of human immunodeficiency virus (HIV) screening in Primary Care: a cluster randomised controlled trial (RCT) and economic analysis

Acronym
RHIVA2

Study objectives
The primary objective is to demonstrate that rapid human immunodeficiency virus (HIV) testing integrated into the GP registration health check, when combined with an educational package for health care professionals, increases the rate of HIV testing and diagnoses over and above usual care.

The secondary objective is to demonstrate an increase in proportion of HIV cases diagnosed during early stages of infection, defined as a CD4 count higher than 200 cells per cubic millimetre.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camden and Islington Community Research Ethics Committee, 18/11/2009, ref: 09/H0722/67

Study design
Pragmatic cluster randomised single-centre controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
Can be found at http://www.ihse.qmul.ac.uk/chsgppc/RHIVA%202/24346.pdf and http://www.ihse.qmul.ac.uk/chsgppc/RHIVA%202/24347.pdf

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS)

Interventions

Intervention surgeries:
The formative phase for intervention surgeries will include the following:
1. Analysis of the educational requirements for GPs nurses and health care assistants
2. Provision of training in performing the rapid point of care HIV test
3. Setting up the operating procedure for HIV testing as an integrative part of the new patient health check
4. Confirmation of referral pathways for newly diagnosed patients into specialist care
5. Establishing the role of the HIV specialist nurse as the key figure to facilitate communication about newly diagnosed patients between clinicians including GPs and the HIV specialist team, the Virology lab and the researchers

Follow-up procedures:
Any patient with a reactive HIV rapid test will be seen by the GP immediately for information; a further test and specialist follow up. The HIV specialist nurse, a member of the clinical management team at the Department of Sexual Health at Homerton Hospital, will liaise with both GP surgeries and the Department of Virology at Barts and The London NHS Trust at least fortnightly to minimise the loss of patients followed up in specialist care. If a patient fails to attend specialist follow up, the HIV research nurse will make appropriate attempts to contact the patient.

Laboratory assessments:
1. Rapid HIV test: The rapid HIV test will be performed using the INSTI HIV-1/HIV-2 Rapid Antibody Test (bioLytical Laboratories, Canada) according to the manufacturer's instructions. The INSTI test device has CE-marking and detects antibodies to the Human Immunodeficiency Virus Type 1 and Type 2. Briefly, 50 micro litres of blood drawn from a finger prick using a pipette is mixed with a Sample Diluent and poured onto a Sample Membrane. Signals are visualised by applying a Colour Developer onto the membrane and by de-staining the background using a Clarifying Solution. Results are available in 60 seconds. A single dot (control) on the Sample Membrane indicates a negative result; an additional blue test dot suggests HIV infection, and any other staining pattern including the absence of any signal indicates an invalid result. For further information, please see http://www.biolytical.com/ourtechnology.html.
2. CD4 counts and viral parameters including HIV viral load, clade and genotype of the virus

Laboratory assessments of immunological and viral endpoints specified in section 8.1.2.1 of this protocol will be performed according to approved standard operating procedures.

Total duration of treatment and follow up:
For patients testing reactive, invalid or inderminate on the Rapid HIV Fingerprick test treatment and follow up could be between 2 weeks and 2 months depending on result. In cases where patients test non reactive, treatment will last only a few moments.

Control Surgeries:
No treatment. Control surgeries will be informed about the most recent specialist recommendations for HIV testing and receive support from the HIV specialist nurse throughout the study period.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure
Rates of new HIV diagnoses: numbers of rapid and standard HIV tests done in new patient health checks

Outcomes are measured quarterly.

Secondary outcome measures
Immunological outcomes:
1. Numbers of patients diagnosed during early HIV infection defined as CD4 count higher than 200 cells per cubic millimetre blood

Viral outcomes:
2. HIV viral load, clade and genotype of the virus at the time of diagnosis as predictors of disease progression

Health service use:
3. Numbers of registering patients
4. Numbers of standard HIV tests done opportunistically
5. Numbers of New Patient Health Checks carried out

Economic outcomes:
6. Cost-effectiveness of the intervention compared to standard of care

Outcomes are measured quarterly.

Overall study start date
01/01/2010

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Individuals aged 16 years or older registering at study practices, either sex
2. Individuals able to undertake the pre-test discussion in English or with a suitable translator

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
23,000

Key exclusion criteria
1. Aged under 16 years
2. Individuals with limited English abilities, who are unable to understand the info sheet or, who are unable to engage with the pre-test discussion for HIV testing
3. Known HIV positive patients

Date of first enrolment
01/01/2010

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts and The London School of Medicine and Dentistry
London
United Kingdom
E1 2AT

Sponsor information

Organisation
Queen Mary's University of London (UK)

Sponsor details
Joint Research and Development Office
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London
England
United Kingdom
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Sponsor type
University/education

Website
http://www.ihse.qmul.ac.uk/chsgppc/RHIVA%202/index.html

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
City and Hackney Primary Care Trust (UK) (ref: PMO 34B)

Funder Name
Department of Health (UK)

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	31/05/2015		Yes	No
Results article	results	01/06/2015		Yes	No