Routine human immunodeficiency virus (HIV) screening for sexually transmitted infection (STI) patients in Cape Town, South Africa

Submission date	Recruitment status	Prospectively registered
14/05/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
31/07/2009	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
18/12/2017	Infections and Infestations	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The impact of provider-initiated (opt-out) human immunodeficiency virus (HIV) testing and counselling of sexually transmitted infection (STI) patients in Cape Town, South Africa: a controlled trial

Study objectives

Does provider-initiated human immunodeficiency virus (HIV) testing and counselling increase HIV test uptake amongst new sexually transmitted infection (STI) patients in an operational, primary health care setting?

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. University of Cape Town, Health Sciences Faculty Research Ethics Committee approved on the 27th July 2007 (ref: 295/2007)
- 2. City Health Department letter of permission to do operational research dated 17th May 2007

Study design

Non-randomised cluster controlled multicentre trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Screening

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

Human immunodeficiency virus (HIV)

Interventions

Provider-initiated (opt-out) HIV testing and counselling (PITC) provided by STI nurses as compared to the standard voluntary counselling and testing provided by lay counsellors. PITC

was implemented for 18 months from April 2006 to Dec 2007. Routine data from the VCT register and the Routine Monthly Report was collected retrospectively for 6 months from April 2007 to December 2007.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. HIV testing rates of new STI patients for a 6-month period from Jan 2007 to June 2007
- 2. Number of new STI patients who tested for HIV divided by total number of new STI patients treated

Secondary outcome measures

- 1. The rate of providers offering the HIV test or pre-counselling patients (irrespective of whether they accept the test or not). Number of new STI patients offered the HIV test /counselled divided by the total number of STI patients treated.
- 2. The rate of patients declining the offer of testing. Number of new STI patients not tested for HIV divided by the total number of new STI patients treated.
- 3. The variability of outcome measures between the clinics. Statistical comparison of the range of clinic outcomes between the intervention and control groups to check for variance.

Overall study start date

01/04/2006

Completion date

30/12/2007

Eligibility

Key inclusion criteria

- 1. Primary health care, public sector clinics
- 2. Geographical location-one clinic per sub-district in Cape Town
- 3. Clinics providing STI treatment for more than 30 new STI patients a month
- 4. Clinics with an average nurse:patient ratio
- 5. All patients assessed for a new episode of sexually transmitted disease at participating public sector primary care clinics. Male and female, mainly adults of reproductive age, but no age limit to who gets treated at the clinics.

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

7 intervention and 14 control clinics

Key exclusion criteria

- 1. Clinics providing an exclusive STI treatment service (not as part of a general primary health care package)
- 2. Clinics where other research is being conducted that may influence the outcome

Date of first enrolment

01/04/2006

Date of final enrolment

30/12/2007

Locations

Countries of recruitment

South Africa

Study participating centre Health Systems Research Unit

Cape Town South Africa 7505

Sponsor information

Organisation

The Medical Research Council of South Africa (MRC) (South Africa)

Sponsor details

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Sponsor type

Research council

Website

http://www.mrc.ac.za/healthsystems/healthsystems.htm

ROR

https://ror.org/05q60vz69

Funder(s)

Funder type

Research council

Funder Name

Department of Science and Technology and The Medical Research Council of South Africa (MRC) (South Africa) - Health Systems Research Unit (ref: 3255)

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 Details type	Date created	Date d added	Peer reviewed	Patient- l? facing?
Results results on impact of provider-initiated (opt-out) HIV testing article	30/01 /2010		Yes	No
Results article results on Implementing a provider-initiated testing and counselling (PITC)	26/08 /2013		Yes	No
results on A comparison of linkage to HIV care after provider-initiated HIV Results testing and counselling (PITC) versus voluntary HIV counselling and testing article (VCT	18/08 /2014		Yes	No