

A randomised controlled study of mouth swab testing versus same-day blood tests for human immunodeficiency virus (HIV) infection in young people attending a young person's community drug service

Submission date

10/12/2007

Recruitment status

No longer recruiting

Prospectively registered

Protocol

Registration date

06/02/2008

Overall study status

Completed

Statistical analysis plan

Results

Last Edited

09/02/2012

Condition category

Infections and Infestations

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

196AA

Study information

Scientific Title

Study objectives

The objective is to determine if providing an oral swab test in the community for blood borne virus testing leads to an increase in subsequent attendance for sexually transmitted infection screening at the Genito Urinary Medicine (GUM) clinic compared to making appointments for young people to attend the clinic for same day HIV testing and sexually transmitted infections (STI) screening.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Leicestershire, Northamptonshire and Rutland Research Ethics Committee (REC) on the 16th January 2007 (ref: 06/Q2501/244).

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Sexually transmitted infections/HIV

Interventions

Control group:

Participants will have a discussion about HIV; they will then be offered an appointment at the GUM clinic. If they agree to an appointment they will be referred to the same-day HIV testing service carried out at the GUM clinic. Here they will be offered blood tests for syphilis, HIV, Hepatitis B and C as per clinic protocol and offered screening tests for genital infections (chlamydia, gonorrhoea and trichomonas). This is the approach which is currently used at the community drug service.

Study group:

Participants will have a pre-test discussion about HIV; they will then be offered an oral swab test for HIV, Hepatitis B and Hepatitis C. The swab tests are sent to the lab for processing with results available in 48 hours. Participants will also be offered an appointment at the Genito Urinary Medicine Clinic for screening tests for genital infections. Negative mouth swab results will result in advice and support regarding sexual health and harm minimisation regarding substance misuse. Positive mouth swab results will result in fast-track referral to the GUM clinic.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The number of individuals attending the Genito Urinary Medicine clinic for screening tests.

Key secondary outcome(s)

1. The number of unvaccinated study participants receiving at least one dose of Hepatitis A and B vaccination
2. The number of unvaccinated study participants receiving 3 doses of the rapid Hepatitis A and B vaccination
3. The number of participants receiving results within a week of testing

Completion date

31/03/2008

Eligibility**Key inclusion criteria**

All young people (under 18 years, male and female) engaged with the young person's substance misuse service deemed competent to provide informed consent.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

18 years

Sex

All

Key exclusion criteria

All young people engaged with the young person's substance misuse service who are deemed not competent to provide informed consent.

Date of first enrolment

01/04/2007

Date of final enrolment

31/03/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Genito-Urinary Medicine Clinic

Derby

United Kingdom

DE1 2QY

Sponsor information

Organisation

Derbyshire Mental Health Services NHS Trust (UK)

ROR

<https://ror.org/02zfxwc21>

Funder(s)

Funder type

Industry

Funder Name

Gilead Sciences Ltd (UK)

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	01/01/2011		Yes	No