# 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	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
10/12/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/02/2008	Completed	[X] Results		
<b>Last Edited</b> 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

Dr Ade Apoola

## Contact details

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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 misue 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

Participant information sheet 11/11/2025 No Yes