

# 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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**Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **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**

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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/04/2007

**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

**Age group**

Child

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

54

**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**

England

United Kingdom

**Study participating centre**

**Genito-Urinary Medicine Clinic**

Derby

United Kingdom

DE1 2QY

**Sponsor information****Organisation**

Derbyshire Mental Health Services NHS Trust (UK)

**Sponsor details**

Bramble House

Kingsway

Derby

England

United Kingdom

DE22 3LZ

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.derbyshirementalhealthservices.nhs.uk/>

**ROR**

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

## Funder(s)

**Funder type**

Industry

**Funder Name**

Gilead Sciences Ltd (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?
<a href="#">Results article</a>	results	01/01/2011		Yes	No