

# Evaluation of cytology and HPV testing for testing for anal intraepithelial neoplasia in high-risk populations in the UK

<b>Submission date</b> 20/09/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 05/01/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-screening-for-anal-cancer-analogy>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

12823

## Study information

### Scientific Title

Evaluation of cytology and HPV testing for testing for anal intraepithelial neoplasia in high-risk populations in the UK: a non-randomised study

## **Acronym**

ANALOGY

## **Study objectives**

The aim of this study is to make an initial evaluation of the utility of offering 'high risk' people testing for anal cancer; to test how easy it would be to recruit the at risk population; to find out what patients feel about screening; and to obtain up to date information for the UK on the numbers of people likely to have an abnormal test result at each stage of the testing process.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

NRES Committee North West Greater Manchester North, 14/05/2012, ref: 12/NW/0204

## **Study design**

Non-randomised study

## **Primary study design**

Interventional

## **Study type(s)**

Screening

## **Health condition(s) or problem(s) studied**

Topic: Infection, Generic Health Relevance and Cross Cutting Themes; Subtopic: Infection (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Infectious diseases and microbiology , Surgery

## **Interventions**

Anal cytology: All participants will be offered testing for evidence of abnormality including anal cytology (liquid based cytology), HPV testing, anal HPV testing.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Evaluation of LBC and HPV testing/typing and anoscopy as potential screening tests at end of study

## **Key secondary outcome(s)**

1. Feasibility of recruitment, screening and follow up
2. Patient acceptability of screening for anal neoplasia
3. Reliable estimates of prevalence of anal cytological abnormality and HPV positivity by type

Measured at end of study

**Completion date**

31/08/2014

## **Eligibility**

**Key inclusion criteria**

1. HIV positive men and women who have anal intercourse attending NHS genitourinary medicine (GUM) clinics
2. Men who have sex with men (MSM), recruited through GUM clinics and specialist general practices
3. Immunosuppressed transplant recipients (men and women) attending transplant follow-up clinics

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Patients with prior history of anal neoplasia

**Date of first enrolment**

01/09/2012

**Date of final enrolment**

31/08/2014

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Oxford Road**  
Manchester  
United Kingdom  
M13 9PL

## **Sponsor information**

### **Organisation**

Central Manchester University Hospitals NHS Trust (CMFT) (UK)

### **ROR**

<https://ror.org/00he80998>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

National Health Service Cancer Screening Programme (UK)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration