

# 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## 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

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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/09/2012

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Planned Sample Size: 1000; UK Sample Size: 1000

**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**

England

United Kingdom

**Study participating centre**

**Oxford Road**

Manchester

United Kingdom

M13 9PL

## **Sponsor information**

**Organisation**

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

**Sponsor details**

St Mary's Hospital

Manchester Royal Infirmary

Oxford Road

Manchester

England

United Kingdom

M13 9WL

**Sponsor type**

Hospital/treatment centre

**ROR**

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

## **Funder(s)**

**Funder type**

Government

**Funder Name**

## 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