

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

Submission date 20/09/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/09/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/01/2017	Condition category Cancer	☐ Individual participant data ☐ 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

Prof Henry Kitchener

Contact details

Oxford Road
Manchester
United Kingdom
M13 9PL
+44 161 306 6000
henry.c.kitchener@manchester.ac.uk

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

Primary study design

Interventional

Study design

Non-randomised study

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