Randomised, double-blind, placebo controlled, phase III, parallel group study in gay men using 5% Imiquimod for the treatment of high-grade anal intraepithelial neoplasia (AIN 2/3)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
12/09/2003		☐ Protocol		
Registration date 12/09/2003	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
17/09/2012	Infections and Infestations			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number N0024115339

Study information

Scientific Title

Study objectives

Is it feasible to treat high-grade anal intraepithelial neoplasia (AIN 2/3) as defined by histological regression and clearance of high-risk human papillomavirus (HrHPV) by topical use of 5% Imiquimod?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Infections and Infestations: Papillomavirus

Interventions

Randomised controlled trial: A. 5% Imiguimod

B. Placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Complete clearance of AIN 2/3 lesions.

Key secondary outcome(s))

Not provided at time of registration

Completion date

30/09/2004

Eligibility

Key inclusion criteria

The study aims to recruit 64 patients on both sites (28 from Homerton).

- 1. Patients will be recruited from the pool of patients already attending the anoscopy clinics at Homerton University Hospital and Bart's and The London NHS Trusts.
- 2. Human Immunodeficiency Virus + (HIV+) patients will have been on antiretroviral combination therapy (HAART therapy) for at least 3 months prior to recruitment.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/10/2002

Date of final enrolment

30/09/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Department of Sexual Health

London United Kingdom E9 6SR

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Homerton University Hospital NHS Trust (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	24/09/2010		Yes	No