

# 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)

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 17/09/2012	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

## Participant information sheet

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

Infections and Infestations: Papillomavirus

### Interventions

Randomised controlled trial:

A. 5% Imiquimod

B. Placebo

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

Complete clearance of AIN 2/3 lesions.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/10/2002

**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

**Age group**

Adult

**Sex**

Male

**Target number of participants**

64

**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**

England

United Kingdom

**Study participating centre**  
**Department of Sexual Health**  
London  
United Kingdom  
E9 6SR

## **Sponsor information**

**Organisation**  
Department of Health (UK)

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.doh.gov.uk>

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

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