ISRCTN96401551 https://doi.org/10.1186/ISRCTN96401551

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
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
17/09/2012

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(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