

Treatment precursor stadia of anal cancer with Efudix-cream in HIV positive homosexual men

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28276

Source

NTR

Brief title

pilot TRAIN trial

Health condition

Anale intraepitheliale neoplasia in HIV-positive patients

Sponsors and support

Primary sponsor: - Academic Medical Center (AMC)

- St. Josef Hospital, Ruhr Universität, Bochum

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

- Histological resolution of AIN

- Relapse rate at 6 and 12 months

Secondary outcome

- Side effects of treatment
- HPV types and load before and after treatment

Study description

Background summary

In this study we will treat about forty HIV+ MSM with intra-anal anal intraepithelial neoplasia (AIN) with local Efudix for a period of 16 weeks. Primary endpoint is histological resolution at 16 weeks. Follow up will take place after 6 and 12 months.

Study objective

5-FU cream is a potential treatment option for intra-anal AIN

Study design

t = 0 start treatment

t= 16 weeks early evaluation

t = 24 weeks: follow up

t = 48 weeks: follow up

Intervention

5-Fluorouracil cream twice a week intra-analy during 16 weeks

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient is >18 years of age
2. Patient has a proven HIV infection
3. Patients is MSM

Exclusion criteria

1. History of anal carcinoma
- 2 .History of chronic bowel disease

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control: N/A , unknown

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-04-2008

Enrollment: 50

Type: Anticipated

Ethics review

Positive opinion

Date: 22-08-2008

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1358
NTR-old	NTR1415
Other	TRAIN trial : MEC 07/318
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A