Treatment of anal intraepithelial neoplasia in HIV-positive patients, a triple-arm randomized clinical trial

No registrations found.

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

Summary

ID

NL-OMON25252

Source
Nationaal Trial Register

Brief title
TRAIN trial

Health condition

Anal intraepithelial neoplasia
Anale intraepitheliale neoplasie

Sponsors and support

Primary sponsor: AMC
Postbus 22660
1100 DD
Amsterdam
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

- Histological resolution of AIN

- Relapse rate of AIN 24, 48 and 72 weeks after treatment

Secondary outcome

- Side effects of treatment

- QALY's, derived from the EQ-5D questionnaire

- Questionnaire sexual functioning: FSFI and IIEF -

- Costs of local treatment of precancerous lesions to prevent severe anal neoplasia

- HPV types and HPV load before and after treatment

- Single nucleotide polymorphisms (SNPs)in genes involved in the recognition of pathogens and the inflammatory response

- Presence of sexual transmitted co-infections

Study description

Background summary

In this study, we will screen 300 HIV+ MSM and women treated at the HIV outpatient clinics of the AMC, at two consecutive years, by performing high resolution anoscopy, with biopsy if lesions are seen.
In case of AIN I-III in anal biopsies patients will be randomized (1:1:1) between three treatment regimens: local treatment of lesions with fluorouracil, imiquimod or with electro-coagulation. Primary endpoint is histological resolution of AIN 4 weeks after the end of treatment.

The primary objective of this study is to establish the preferred treatment of AIN to prevent the development of severe anal neoplasia (persistent AIN III or anal carcinoma) in HIV+ MSM and HIV+ woman.

Study design

t = 0 screening

treatment during 16 weeks

early evaluation at twenty weeks

follow up at 40, 64 and 88 weeks

Intervention

- Cauterisation, max 5 times in 16 weeks

- Imiquimod cream, 1 sachet 3 times a week

- 5-Fluorouracil cream, 1 g, twice a week

- After inclusion of 25 patients in each treatment arm an interim analysis will be performed to evaluate side effects.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient is > 18 years of age

2. Patient has a proven HIV infection

3. Patient is MSM or woman. Women of child- bearing potential should use highly effective methods of birth control during the duration of the study.

Exclusion criteria

1. History of anal carcinoma

2. History of chronic bowel disease

3. Life expectancy < 12 months

4. Pregnancy or lactation

5. Active i.v. drug user

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-02-2008

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	NL1191
NTR-old	NTR1236
Other	MEC : 07/318
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A