

# HIV acceptance test in cervical dysplasia at the time of colposcopy

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON20916

### Source

NTR

### Brief title

HIV acceptance test in cervical dysplasia

### Health condition

hiv  
cervical dysplasie

## Sponsors and support

**Primary sponsor:** Erasmus MC

**Source(s) of monetary or material Support:** Aidsfonds Nederland

## Intervention

## Outcome measures

### Primary outcome

Acceptance of the HIV rapid test by the patient.

### Secondary outcome

Number of positive tests.

- Uptake of HIV testing in the various clinics.
- Uptake of HIV testing in relation to the severity of the dysplasia.
- Feasibility of the HIV rapid test within the current colposcopic setting.

## Study description

### Background summary

Erasmus MC launched the # aware.hiv initiative this year. This initiative is supported by the Federation Medical Specialist (FMS) and aims to identify patients with an undiagnosed HIV infection so that they can receive adequate treatment. This # aware.hiv project is included within one of the core themes of the FMS (the right care in the right place). Detection is done by testing patients for HIV via so-called HIV indicator diseases. These indicator diseases include conditions where the chance of an undiagnosed HIV infection is  $> 0.1\%$ . Within gynecology, cervical dysplasia and cervical carcinoma are important HIV indicator diseases. All new patients with cervical cancer at the gynecological oncology outpatient clinic of Erasmus MC are tested for HIV.

According to the international literature, cervical dysplasia is also an indicator disease and therefore HIV testing should be standard in women with cervical dysplasia. In practice, an HIV test is rarely or never performed in this group. A common reason among doctors is the perceived reluctance to test given the potentially negative annotation that HIV testing has for patients. It is striking, however, that in the Netherlands the risk of an HIV infection is much lower among pregnant women than with HIV indicator diseases. Nonetheless screening for HIV is already common practice for pregnant women. This supports the assumption that the alleged reluctance to perform an HIV test is unfounded. Acceptance of an HIV test among women with cervical dysplasia is also expected to be high. The acceptance of HIV tests in women with cervical dysplasia is unknown in the Netherlands. The international literature is very variable with a variation of 8-100% acceptance. Knowing how women in the Netherlands feel about having an HIV test for this indicator disease can help doctors to get the right care in the right place.

We want to use this study to gain more understanding about the acceptance rate among patients. This information can help doctors to better implement national and international guidelines on HIV and cervical dysplasia in the Dutch setting. In addition, we want to see whether a simple HIV rapid test can be used in current practice to improve possible implementation in our guideline.

### Study objective

the acceptance of HIV test in cervical dysplasia during colonoscopy is high. ( $>80\%$ )

### Study design

1 year

### **Intervention**

none

## **Contacts**

### **Public**

Erasmus MC  
Ralf van de Laar

0650032145

### **Scientific**

Erasmus MC  
Ralf van de Laar

0650032145

## **Eligibility criteria**

### **Inclusion criteria**

- Cytological result PAP 3a1 or higher and / or colposcopic clinical impression of at least CIN I
- Able to read / write Dutch / English

### **Exclusion criteria**

- Under 18 years of age
- Recent HIV testing (<6months)

## **Study design**

### **Design**

Study type: Observational non invasive

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Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	750
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Yes

## Ethics review

Positive opinion	
Date:	11-03-2021
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	NL9405

**Register**

Other

**ID**

METC EMC : MEC-2021-0289

## Study results