

# An open, prospective, comparative clinical trial to evaluate the improvement of the colposcopist with the use of DySIS™ compared to conventional colposcopy

<b>Submission date</b> 11/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/01/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> 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**  
N/A

## Study information

**Scientific Title**

An open, prospective, comparative clinical trial to evaluate the improvement of the colposcopist with the use of DySIS™ compared to conventional colposcopy

**Acronym**

The DySIS™ study

**Study objectives**

Primary:

DySIS™ has a higher sensitivity in discriminating High Grade (HG) from Low Grade (LG) lesions and non-neoplastic tissue as well as in selecting the most atypical site for biopsy sampling, through digital documentation and interpretation of colposcopic images and the correlation with visual interpretation and histology (golden standard) than conventional colposcopy.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The protocol of the DySIS study was approved on 6th July 2007 by the local medical ethics committee (Medisch Ethische Toetsingscommissie VU medisch centrum) in Amsterdam, The Netherlands (ref:2007/098).

**Study design**

Non-randomised, controlled, parallel group, multicentre trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Cervical Intraepithelial Neoplasia (CIN)

**Interventions**

1. Besides conventional colposcopy, colposcopy with DySIS™.
2. hrHPV, viral load, E6/E7 antibodies and p16INK4a testing
3. At random biopsy
4. Measurement of the lesion size

For all the subjects, all the measurements are done during one visit to the outpatient clinic. Therefore, the primary and secondary outcomes are also measured during this visit.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Primary endpoint:

Consensus in DySIS™ colposcopic and conventional colposcopic impression of a lesion and histology (golden standard).

### **Key secondary outcome(s)**

Secondary endpoints:

1. Consensus in DySIS™ colposcopic and conventional colposcopic localisation of the optimal biopsy point and histology (golden standard)
2. Consensus of DySIS colposcopic and conventional colposcopic impression of a lesion and HPV GP5+/6+ Polymerase Chain Reaction (PCR) testing and hybrid capture
3. Higher HPV viral load by a larger, hrHPV positive, lesion (through [semi]-quantitative, real-time PCR-based viral load assessment)
4. A relation between p16INK4a and the size of the lesion
5. A relation between viral load and hrHPV antibody titres

### **Completion date**

10/10/2007

## **Eligibility**

### **Key inclusion criteria**

1. Female
2. 18 years of age or older
3. Intact cervix (no history of Loop Electrosurgical Excision Procedure [LEEP] or surgical treatment involving damage to the transformation zone of the cervix)
4. Study group only: an abnormal cytological test result and/or positive high-risk Human Papillomavirus (hrHPV) test
5. Control group only: to be able to undergo a colposcopy (according to the gynaecologist)
6. Sufficient knowledge of the Dutch or English language
7. Able to understand the content of the study (according to the gynaecologist)
8. Signed informed consent form

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Female

### **Key exclusion criteria**

1. History of surgery on the cervix
2. Previous pelvic radiotherapy
3. Pregnancy or pregnant in the last three months
4. Breast-feeding, or breast-feeding in the last three months
5. Heavy bleeding (menstruation or other) or excessive vaginal discharge in which a colposcopy cannot be performed. Enrolment in the study protocol will be postponed until the condition is resolved according to the gynaecologists medical judgment
6. Self-referring women without an abnormal smear

**Date of first enrolment**

10/04/2007

**Date of final enrolment**

10/10/2007

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre**

Vrije Universiteit Medical Centre (VUMC)

Amsterdam

Netherlands

1007 MB

## Sponsor information

**Organisation**

VU University Medical Centre (The Netherlands)

**ROR**

<https://ror.org/00q6h8f30>

## Funder(s)

**Funder type**

Industry

**Funder Name**

VU University Medical Centre (The Netherlands)

## Funder Name

Forth-Photonics (Greece)

# 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?
<a href="#">Results article</a>	results	01/12/2015	04/01/2021	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes