

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

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

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.humavac.nl> (onder 'onderzoek')

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Primary endpoint:

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

Secondary outcome measures

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

Overall study start date

10/04/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

400

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)

Sponsor details

Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

Sponsor type

Hospital/treatment centre

Website

<http://www.vumc.nl/english/#http://www.vumc.nl/english/>

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**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**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	01/12/2015	04/01/2021	Yes	No