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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	[_] Prospectively registered [_] Protocol
Registration date 11/04/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 05/01/2021	**Condition category** Cancer	[_] 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

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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