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

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Primary:To validate the latest version of DySIS 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...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31605

Source
ToetsingOnline

Brief title
The DySIS* study

Condition

- Other condition
- Reproductive neoplasms female malignant and unspecified

Synonym
Cervical intraepithelial neoplasia / Forerunner lesions of cervical cancer

Health condition

pre-maligne cervix afwijkingen

Research involving
Human

Sponsors and support

Primary sponsor: Forth Photonics
Source(s) of monetary or material Support: Ministerie van OC&W,Forth Photonics

Intervention

Keyword: Cervical Intraepithelial Neoplasia (CIN), Digital colposcopy, Human papillomavirus, P16INK4a

Outcome measures

Primary outcome

Consensus in DySIS colposcopic and conventional colposcopic impression of a

lesion and histology (*golden standard*).

Secondary outcome

- Consensus in DySIS colposcopic and conventional colposcopic localization of

the optimal biopsy point and histology (*golden standard*).

- Consensus of DySIS colposcopic and conventional colposcopic impression of a

lesion and HPV GP5+/6+ PCR testing and hybrid capture.

- Higher HPV viral load by a larger, hrHPV positive, lesion.

- A relation between p16INK4a and the size of the lesion.

- A relation between viral load and hrHPV antibody titers.

Amendment:

- Relation between (percursors of) adenocarcinoma of the cervix and hrHPV

positivity in women with normal cytology.

- Relation between visible colposcopic lesions and the histological outcome of

the endocervical sample.

- Relation between hrHPV positivity for the type(s) 16, 18 and/ or 45 with

normal cytology and the outcome of an endocervix sample

- Number of endocervical samples which are unstatisfactory when using the

Kevorkian endocervix curette

- Difference in the detection of endocervical lesions between women who are

hrHPV positive with negative cytology aged younger than 35 years and women aged

35 years or older.

Study description

Background summary

DySIS*, developed by Forth-Photonics, is an abbreviation for Dynamic Spectral Imaging System. With this system it is possible to digitally evaluate and save colposcopic images.

Study objective

Primary:
To validate the latest version of DySIS 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*).

Secondary:
o Validation of the latest version of DySIS in reducing both inter- and intra-observer disagreement
o To investigate (feasibility study) the ability of DySIS to identify hrHPV-positive lesions
o To demonstrate the correlation between the size of a cervical lesion and hrHPV viral load.
o Comparison of the performances of conventional colposcopy and DySIS in in vivo identifying hrHPV-positive cervical lesions.

o Correlation of the size of a cervical lesion and p16INK4a expression.
o To demonstrate the relation between viral load and hrHPV antibodies.

Primary objective of the amendment:
To assess the added value of an endocervical sample as a screening tool for (precursors of) adenocarcinoma of the cervix in women positive for hrHPV with negative cytology compared to women negative for hrHPV with negative cytology.

Study design

The study is designed as an open, prospective, comparative clinical trial. The results of colposcopy performed with DySIS will be compared with:
1. The grading of the referral Pap-test.
2. The evaluation of the lesion by the colposcopist using DySIS as a conventional colposcope.
3. Histology.
4. HPV GP5+/6+-PCR testing.

The size of a possible lesion (determined after processing the DySIS images) will be compared with:
5. HPV viral load measurements.
6. p16INK4a expression.

Furthermore,
7. HPV E6/E7 antibodies will be compared with viral load levels
8. Endocervical sample

The study group will also be compared with a control group with the aim to test DySIS in a group of women which is not disease enriched. This control group will have to meet the same inclusion and exclusion criteria as the study group, but the women may not have an abnormal cytology test result. In this group, the chances are substantial, that no (CIN) lesions will be seen during the colposcopy.

The clinical trial will be divided in three phases:
1. Preliminary data collection
2. Main Study
3. Review of the collected data

Study burden and risks

Participation in this trial means that at least one, but possible two extra cervical biopsies are taken. From the women in the control group, also an endocervical sample will be taken. This has the disadvantage that subjects more often than if they do not participate, are exposed to biopsy/sample taking. The advantage is, since all the biopsies/samples are studied in the laboratory for

histological lesions, the chance increases that no lesions are missed.

It is not pleasant to have a biopsy or endocervical sample taken, but it is part of the regular colposcopic examination. Although women often express some minor pain, it is considered bearable and the blood loss is generally minimal. A 10 mL bloodsample is also drawn. This sometimes leads to side-effects, but generally they are not severe and do not last for long.

Despite of the aforementioned, the burden of this trial is, to our opinion, minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Female
- At least 18 years of age
- Intact cervix (no history of LEEP or surgical treatment involving damage to the transformation zone of the cervix).
- To be able to undergo a colposcopy.
- Study group only: An abnormal cytological test result and/or positive hrHPV test.
- Controle group: No abnormal cytology or positive hrHPV test.

Exclusion criteria

- History of surgery on the cervix
- Previous pelvic radiotherapy.
- Pregnancy or pregnant in the last 3 months.
- Breast-feeding, or breast-feeding in the last 3 months.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-06-2007
Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

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
ISRCTN	ISRCTN66112760
CCMO	NL16292.029.07