Protocol for Cervical Cancer Screening FCM Feasibility Study in EU. Measurement of the cell proliferation status / detection of cervical lesions for rapid screening (high throughput) of Cervical Cancer with the LC-1000

Published: 18-02-2016
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The objective of this feasibility / pilot study is to clarify the clinical performance and economic efficiency of the cervical cancer screening system which is under development at Sysmex Corp Japan. In this study, the objective should be achieved...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON43409

Source
ToetsingOnline

Brief title
Protocol for Cervical Cancer Screening FCM Feasibility Study in EU.

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cervical cancer

Research involving

Human

Sponsors and support

Primary sponsor: Sysmex Europe GmbH
Source(s) of monetary or material Support: Sysmex Europe GmbH

Intervention

Keyword: cervical cancer, flowcytometry, screening

Outcome measures

Primary outcome

The histology results from the routine cytology positive sample will be compared to the sensitivity of other tests (cytology, LC-1000 and HPV) (primary evaluation criteria). To verify the clinical screening performance of the FCM system (LC-1000), the cytology result of the routine cytology sample and the LC-1000 result will be compared, sensitivity and specificity for advanced cervical lesions (CIN2 lesions or higher stages) finally calculated (secondary evaluation criteria).

Secondary outcome

none

Study description

Background summary

see below

Study objective

The objective of this feasibility / pilot study is to clarify the clinical performance and economic efficiency of the cervical cancer screening system which is under development at Sysmex Corp Japan. In this study, the objective

should be achieved by executing reliable tests with (1) strict operational sampling, (2) well-managed use of the samples, (3) comparison with high-quality cytology diagnosis, and (4) considering implementation to screening workflow with clarifying its economic efficiency.

Study design

In this feasibility / pilot study, which will need the consent of the medical ethics review board of the hospital, 500 women over 20 years of age who have had cervical cytology tests, will be included. All women included in the study need to have signed an informed consent document and then the algorithm set by earlier pilot studies will be validated by comparing results from cytology / histology, the FCM system (LC-1000) and HPV testing. This algorithm is schematically shown in the protocol (page 5).

Study burden and risks

During the routine gynaecological survey, a second cervical smear will be taken if a first smear is necessary for further diagnosis. Burden and additional risks will be considered as 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

females older than 20 years who visit a gynaecologist for a cervical smear

Exclusion criteria

females younger than 20 years, pregnant women, women who were deemed inappropriate by their gynecologist to participate in this study, and women who underwent cervical conisation* (or total hysterectomy). However, after a certain period (approx. 6 month) following cervical conisation, it*s possible to participate in this study at the discretion of the gynecologist.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2016
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2016
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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
CCMO	NL55793.096.15