Preferential study of women with adnexal masses considering frozen section diagnosis.

Published: 27-04-2007
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The objective of the study is to examine the opinion of women about the accuray of frozen section diagnosis. A important question is how women feel about a second operation in case of a false negative testresult.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ovarian and fallopian tube disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30526

Source
ToetsingOnline

Brief title
Preferential study frozen section diagnosis.

Condition

- Ovarian and fallopian tube disorders

Synonym
frozen section diagnosis at ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Máxima Medisch Centrum
Source(s) of monetary or material Support: eigen budget

Intervention

Keyword: Adnexal mass, frozen section diagnosis, preferential study

Outcome measures

Primary outcome

The questionnaires will be analysed.

Secondary outcome

not applicable

Study description

Background summary

To reach optimal surgical treatment of ovarian masses it is important to differentiate between the malignant ovarian masses and benign ovary. During surgery frozen section diagnosis can be useful. The pathologist examines the most suspected part of the tumor and judges whether it is benign or malignant. This fast type of examination has a high specificity with acceptable sensitivity. The diameter of the tumor and its histological type influence the accuracy of frozen section diagnosis. In case of a false negative testresult the surgeon removes just one of the ovaries under suspicion of benign pathology. After one week the parafine diagnosis shows malignancy and the patient needs a second operation in which the other ovary, the uterus and omentum have to be removed, lymfnode sampling has to take place and biopsies of the peritoneum.

Study objective

The objective of the study is to examine the opinion of women about the accuray of frozen section diagnosis. A important question is how women feel about a second operation in case of a false negative testresult.

Study design

All women who are scheduled for surgery because of an ovarian mass in the Maxíma Medical Centre are eligible for inclusion into the study. The gynecologist provides verbal and written information to the patient. If the patient agrees to cooperate the study nurse contacts the patient by telepfone. The study nurse invites the patients for a visit at the out patients'

department. After informed consent has been signed, the study nurse offers help during answering the questionnaire. The study nurse is not informed about the kind of pathology of the ovarian mass and consequently not aware of a possible increased risk of malignancy. After six weeks the patient is asked to answer the questionnaire again.

Study burden and risks

There are no risks for the study population. Treatment of the patient is independent of the questionnaire. The study nurse is not informed about the kind of pathology of the ovarian mass and consequently not aware of a possible increased risk of malignancy.

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

patients with an ovarian mass, prepared to answer a questionnaire

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	27-04-2007
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL12470.015.06