Hysterectomy with TUbectomy (HYSTUB) study

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Does salpingectomy during a hysterectomy cause POF? Secundary: what is the incidence of premalignant changes within Fallopian tubes of women without a hereditary high risk to develop serous carcinoma?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Obstetric and gynaecological therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40051

Source
ToetsingOnline

Brief title
HYSTUB

Condition

- Obstetric and gynaecological therapeutic procedures

Synonym
premature ovarian Faillure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: hysterectomy, ovarian carcinoma, ovarian faillure, tubectomy

Outcome measures

Primary outcome

concentration AMH, FSH and oestradiol pre- and six months postoperatively.

Does a salpingectomy during hysterectomy for benign indications change hormonal status significantly, indicating a shift towards menopausal status?

Secondary outcome

What is the incidence of premalignancies in Fallopian tubes from women not at hereditary high risk to develop serous carcinomas? Is there a difference in quality of life (QoL) between the two groups?

Study description

Background summary

recent studies in women at hereditary high risk to develop ovarian cancer indicate that high grade serous carcinomas arise from (ectopic and dysplastic) tubal epithelium. Historically, in pre-menopausal women undergoing a hysterectomy for benign indications (such as bleeding disorders, fibroids and adenomyosis) adnexa, including the Fallopian tubes, are usually left in situ. However removing the tubes during a hysterectomy potentially prevents the development of serous ovarian carcinomas. Such a simple preventive procedure should avoid serious adverse effects of adnexectomy, like premature ovarian failure (POF).

Study objective

Does salpingectomy during a hysterectomy cause POF? Secundary: what is the incidence of premalignant changes within Fallopian tubes of women without a hereditary high risk to develop serous carcinoma?

Study design

This is a randomised controlled trial in which will be randomised between salpingectomy or no salpingectomy during a hysterectomy for benign indication.

Intervention

One group will undergo a regular hysterectomy only (either vaginal, abdominal or laparoscopically) (=control group). The other group will receive a regular hysterectomy including a bilateral salpingectomy (case group).

Study burden and risks

preoperative: two extra blood fials (2 x 5 ml). Six months post operative: extra visit for two fials blood (2 x 5ml). It might be that in the groups of women that receive a salpingectomy the risk of serous carcinomas is diminished.

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

Otherwise healthy women undergoing hysterectomy for benign indications (eg. bleeding disorder, fibroids, adenomyosis) without a family history of ovarian / tubal / breast cancer, will be asked to participate.

Exclusion criteria

Family history of cancer, history of any form of cancer

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-06-2013
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	21-08-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	31-10-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-08-2014
Application type:	Amendment
Review commission:	METOPP: Medisch Ethische Toetsing Onderzoek bij Patienten en Proefpersonen (Tilburg)
Approved WMO Date:	23-12-2014
Application type:	Amendment
Review commission:	METOPP: Medisch Ethische Toetsing Onderzoek bij Patienten en Proefpersonen (Tilburg)

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	NL39317.028.12