

# Retro-HOPPSA (Hysterectomy and Opportunistic salpingectomy)

## Research plan

*A comparison of performed hysterectomy vs. hysterectomy with concomitant bilateral salpingectomy on benign indications in Sweden 1998 - mid-2016.*

### Background

Ovarian cancer is a considerable cause of morbidity and mortality around the world. Every year > 230 000 women are diagnosed worldwide and >150 000 die from the disease (1). In recent years a new theory has been put forward where the salpinx play a critical role in the formation and spread of ovarian cancer (2, 3). Studies from Denmark and Sweden have found a decreased incidence of ovarian cancer in women who have had salpingectomy or ligation of the salpinx compared with women who have not undergone surgery (4, 5). These findings have led to an increasing number of opportunistic salpingectomies when performing a hysterectomy for benign reasons in many parts of the world. This despite the fact that only a few minor studies have been performed to evaluate any increase in complications in increasing the surgical field. ( 6, 7). No study has been performed in Sweden on this topic but a new R-RCT (Register-based Randomized Controlled Trial) is starting in 2017, Hysterectomy and Opportunistic Salpingectomy – “HOPPSA”. The aim is to study differences in complications both short and long term as well as effects on ovarian function in women <55 years of age in Sweden, randomized to either have hysterectomy or hysterectomy and concomitant bilateral salpingectomy(BS).

### Objectives

In an observational cohort study analyse data from GynOp from 1998 to mid-2016 to describe:

- Changes in frequency of opportunistic salpingectomy in performing hysterectomy for benign indications until 2016
- Complications per- and postoperatively in the different surgical procedures.
- Difference in approach at different hospitals in Sweden.
- Difference in indications and demographics between women subjected to opportunistic salpingectomy or not at the time of hysterectomy.
- Incidence of adnexal surgery subsequent to hysterectomy with or without concomitant salpingectomy

### Materials and Methods

In Sweden there is a nation-wide quality register to which 70% of performed gynaecological surgeries are reported, the Quality Register of Gynaecological Surgery (a.k.a. GynOp- registret). Information is registered from patients through questionnaires preoperatively, at 8 weeks postoperatively and 1 year postoperatively. The gynaecologist adds information to the register upon decision to perform surgery, at surgery, at discharge from hospital and on assessing the postoperative questionnaires from the patients. In this registry there is data from 1997 onwards and it is an excellent tool to visualise different surgical methods, complications, changes over time etc.

We plan a retrospective observational cohort study based on data reported to GynOp. Included are women <55 years of age who have had hysterectomy or hysterectomy and bilateral salpingectomy for benign reasons from

1998 to mid-2016. We will analyse differences in indications to perform surgery, time in surgery, per and postoperative complications (damage to other organs, bleeding, postoperative infections, postoperative rupture of the surgical wound), time on sick-leave and need for oestrogen supplements preoperatively vs. 1 year postoperatively and the incidence of subsequent adnexal surgery between the two groups. We will also describe the demographics in the two groups regarding age, preoperative functional status, smoking etc.

## Statistics

For descriptive statistics mean, SD, median and interquartile range (IQR) will be used.

For comparison between two groups Student's t-test or Mann-Whitney U-test will be used for continuous variables, Mantel-Haenszel Chi Square test for ordered categorical variables and Fisher's exact test or Chi2 test when applicable, for proportions. For dichotomous outcomes two-sided 95% CI for the difference in proportions between the groups will be calculated as well as risk ratios with 95% CI. To compare groups and control for confounding variables multiple logistic regression models will be used. If applicable, multiple imputation and propensity score matching will be applied.

## Ethical considerations

In this study we require information from a nationwide registry. The women who have contributed to the data will not benefit directly from the study, but if their data can add to the body of evidence regarding opportunistic salpingectomy at the time of hysterectomy it will contribute to equal care. This study is a means towards deciding if it is ethically correct to perform a slightly more extensive surgery in hope of preventing a disease that only a minority of those subjected would succumb to.

Data is analysed on the GynOp server with no access to personal identification of the subjects, in according with the registry's routines. There is no direct negative impact for the patients who have contributed with data to the registry.

## Impact

Increasing the knowledge on the clinical effects of the increased frequency of opportunistic salpingectomy.

## References

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