Plan Overview

A Data Management Plan created using DMPonline

Title: MISSION-O – Menopausal impact of opportunistic salpingectomy for prevention of ovarian cancer

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Project abstract:

Most ovarian cancers (OC) are now believed to arise from the Fallopian tube. Removing Fallopian tubes at other gynaecologic procedures i.e., opportunistic salpingectomy (OS), is advocated for OC prevention. Our randomised trial “Hysterectomy and opportunistic salpingectomy” (HOPPSA) evaluates surgical safety and menopausal symptoms after OS. However, the impact of OS on age at menopause remains unknown as high-quality prospective trial data are lacking. This is critical, as early menopause has significant detrimental long-term health consequences.

Aim: To estimate the impact of OS on age at menopause.

P: Women <55 years undergoing benign hysterectomy

I: Salpingectomy

C: No salpingectomy

O: Age at menopause

Women in HOPPSA (2,700) will be invited to donate blood samples twice: 1-8 and 2-9 years post-surgery. Sampling will be performed by self-sampling of capillary blood on Dried Blood Spot cards. Differences in serum follicle-stimulating hormone (FSH) distribution between arms will be used to estimate impact on menopause, adjusted for age, centre, operative route and time to blood sampling. The mean age difference will be estimated by modelling, using control FSH levels from the Women’s Health Across the Nation (SWAN) cohort study.

Patient benefit: Our study will provide high-quality prospective evidence on impact of OS at hysterectomy on menopausal age. Critically, this will inform clinical guidelines and decision-making for women considering OS in Sweden and world-wide.

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Copyright information:

MISSION-O – Menopausal impact of opportunistic salpingectomy for prevention of ovarian cancer

General Information

Project Title

MISSION-O – Menopausal impact of opportunistic salpingectomy for prevention of ovarian cancer

Project Leader

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Registration number/corresponding

Ethical approval, Dnr. 2025-08086-01
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ClinicalTrials.gov Identifier: NCT07423143

Version

1.0

Date

2026-03-17

Description of data – reuse of existing data and/or production of new data

How will data be collected, created or reused?

Participants (n=2700) from the register-based randomised controlled trial (R-RCT) HOPPSA: Hysterectomy and Opportunistic Salpingectomy (https://www.gynop.se/hoppsa/) in Sweden will be invited to the study. In HOPPSA women <55 years undergoing benign hysterectomy were randomised to either salpingectomy or no salpingectomy. Primary outcomes in HOPPSA are surgical complications

and menopausal symptoms.

Data regarding preoperative health data, randomisation allocation, performed surgery, and complications will be retrieved from the HOPPSA dataset, which was collected using the Swedish National Quality Register of Gynecological Surgery (GynOp) (https://www.gynop.se). Moreover, prior gynaecological surgery and baseline health data at surgery will be retrieved.

After informed consent, participants in MISSION-O will answer a questionnaire regarding current health information using LimeSurvey held by Direkttest Sverige AB requiring multi-factor authentication. In some instances paper-questionnaires will be provided and manually entered. The questionnaire is developed in several steps in collaboration with representatives from a Public and Patient Involvement group. It includes information necessary for follicle-stimulation hormone (FSH) evaluation (e.g. hormonal treatment, gynaecological surgery, smoking, BMI) as well as the validated Self-Administered Comorbidity Questionnaire (SCQ) (Sangha et al., 2003).

Participants meeting criteria for blood sampling will perform self sampling of capillary blood for FSH analysis twice, with 12 months apart.

References:

Sangha, O., Stucki, G., Liang, M. H., Fossel, A. H., & Katz, J. N. (2003). The Self-Administered Comorbidity Questionnaire: a new method to assess comorbidity for clinical and health services research. *Arthritis and rheumatism*, *49*(2), 156–163. https://doi.org/10.1002/art.10993

What types of data will be created and/or collected, in terms of data format and amount/volume of data?

We will collect and create numeric data with databases containing background information, randomisation allocation, complications, data from study questionnaires, and FSH-values.

Data will be stored as

- Excel spread sheets
- CSV format
- Statistical data in R in text-format
- Statistical data in SPSS in .sav format.

Background numerical data from GynOp - 10 GB

Excel spread sheets containing data from questionnaires and blood tests - 1 GB

Statistical data for analysis in R and SPSS - 50 GB

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and format for descriptions of the content, collection method, etc.?

The data has been/will be collected using:

1. The Swedish National Quality Register for Gynecological Surgery (GynOp: https://www.gynop.se/home/): Pre-surgical health information, information regarding surgical procedures, and complications
2. Questionnaires: Health data at self-sampling for FSH analysis
3. Results of FSH analysis

In GynOp and Questionnaires for Health data at self-sampling, all data collection is regularly checked for accuracy and completeness. Up to three reminders are sent if forms are not filled out. Blood samples are controlled for adequate sample. Results will be checked for values out of reasonable range.

The data quality will be upheld by .xls.

The project will follow the folder structure suggested by Umeå University at https://www.umu.se/forskare/planera-och-genomfora/hantera-forskningsdata/samla-och-organisera-data/universitetets-mall-for-mappstruktur/. Additional information will be documented in a "readme" text file.

The research data and metadata will be added to researchdata.se using the SND metadata profile: Medical and Health Sciences which is described at Zenodo: https://zenodo.org/records/8355758.

Controlled vocabulary such as ICD-10, MESH terms and Systematised Nomenclature of Medicine – Clinical Terms (SNOMEDCT) or European Language och Social Science Thesaurus (ELSST) where applicable will be used during the project for documenting the process.

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

Instruments for FSH analysis will be regularly calibrated by the accredited laboratory according to local routines.

Data validation functions in excel will be used.

Data entry will be automated using digital questionnaires. Missing entries will be highlighted for the research person to fill out, but are not obligatory. Manually entered data from paper questionnaires will be validated by a research nurse.

Data entry in the questionnaires has limits for entries within reasonable ranges.

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

An information classification and risk and vulnerability analysis has been conducted in consultation with the data protection officer at Umeå University.

Data will be stored in compliance with the university policy at safe university servers. Data backup will be regularly made.

https://www.umu.se/en/researcher/templates-and-tools/software-and-services/tools-for-collaboration-and-data-storage/

https://www.umu.se/en/researcher/plan-and-implement/security-when-conducting-research/

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and personal data, for example?

Access to data will be limited to persons who will process data. Access will be controlled by the principal investigator Annika Idahl. Data will be stored and processed pseudonymically. The code key

will be kept in a separate space in the university safe servers, where only the principal investigator will have access.

More information: https://www.umu.se/en/researcher/plan-and-implement/manage-research-data/research-data-an-overview/research-data-with-high-protection-value/

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

Informed consent is obtained before collection of personal and sensitive data.

Personal and sensitive data is pseudonyminised using a digital tool providing the participant with a 6 digit study ID at consent.

Personal data and sensitive data will be handled in accordance with the university's recommendations, rules and regulations, and following GDPR, as well as the Public Access to Information And Secrecy Act (OSL).

https://www.umu.se/en/researcher/plan-and-implement/manage-research-data/research-data-an-overview/research-data-with-high-protection-value/

A personal data processing agreement has been signed between Umeå University and Direkttest. A personal data processing agreement will be signed between Umeå University and Queen Mary University of London before any data transfer. The data is owned by Umeå University.

How is correct data handling according to ethical aspects safeguarded?

HOPPSA participants will be recontacted and invited to provide self-sampled blood tests at two time points. Legal advice confirms GDPR compliance. Unique personal identity numbers will be securely linked with the Swedish Population Register to retrieve updated address and vital status data. Participants will receive study information by digital mailbox or by post and provide fresh informed consent.

The project has been reviewed by the Swedish Ethical Review Authority, see ethical approval: Dnr 2025-08086-01.

The research follows the European Code of Conduct for Research Integrity as well as the recommendations by the Swedish Research Council. Furthermore The World Medical Association Declaration of Helsinki principles for ethical research is used.

https://allea.org/wp-content/uploads/2023/06/European-Code-of-Conduct-Revised-Edition-2023.pdf

https://www.vr.se/english/analysis/reports/our-reports/2025-07-03-good-research-practice-2024.html

https://www.wma.net/policies-post/wma-declaration-of-helsinki/

Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes and limitations on the access to and

reuse of data to be considered?

Under Swedish law, individual-level health data containing potentially identifiable and sensitive patient information cannot be shared publicly. Metadata will be published in a research data repository. Researchers may request access to the data; such requests will be subject to a formal secrecy assessment in accordance with the Swedish Act on Public Access to Information and Secrecy (2009:400) and applicable ethical approvals.

Metadata publication site: https://researchdata.se/en

Research data will be stored in Skyddade dokument: https://www.umu.se/en/researcher/templates-and-tools/software-and-services/tools-for-collaboration-and-data-storage/

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

Research data will be archived at the Department of Clinical Sciences, Umeå University, according to established principles at Umeå University.

https://www.umu.se/en/researcher/plan-and-implement/manage-research-data/retain-research-data/archiving-retaining-and-deleting-data/

The Umeå University Retention and Deletion Plan will be followed: https://www.umu.se/en/legal-framework/archive-and-registry/retention-and-deletion-plan-conducting-research/

Will specific systems, software, source code or other types of services be necessary in order to understand, partake of or use/analyse data in the long term?

To access research data, the programs Word, Acrobat Reader, SPSS and Microsoft Excel will be needed.

How will the use of unique and persistent identifiers, such as a Digital Object Identifier (DOI), be safeguarded?

Research metadata will be shared via researchdata.se and thus assigned a DOI.

Responsibility and resources

Who is responsible for data management and (possibly) supports the work with this while the research project is in progress? Who is responsible for data management, ongoing management and long-term storage after the research project has ended?

PI: Annika Idahl, annika.idahl@umu.se. Data capture, metadata production, data quality, storage and backup, data archiving and data sharing. Responsible for implementing the DMP.

Doctoral student: Sara Knip, sara.knip@umu.se. Data capture, metadata production, data quality, storage and backup, and archiving.

Data manager: Per Liv, per.liv@umu.se. Data capture, meta data production and data quality.

Statistician: Adam Brentnall, a.brentnall@qmul.ac.uk. Data quality, meta data production, analyses.

DMP will be reviewed and, if necessary, revised on a yearly basis.

Department of Clinical Sciences, Umeå University, are responsible for providing archiving resources for data material.

https://www.umu.se/en/legal-framework/archive-and-registry/retention-and-deletion-plan-conducting-research/

What resources (costs, labour input or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)? What resources will be needed to ensure that data fulfil the FAIR principles?

Time will be allocated to create a catalogue post when the project has ended.