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# Can ovarian cancer detection be improved using AI-driven diagnostic support applied to ultrasound images?

**Submission date**
26/03/2023

**Recruitment status**
Recruiting

**Registration date**
01/04/2023

**Overall study status**
Ongoing

**Last Edited**
28/05/2024

**Condition category**
Cancer

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Ovarian tumors are common and their management is dependent on the risk of malignancy. Patients with malignant ovarian tumors benefit from being referred to a gynecologic oncologist for debulking surgery, indicating higher survival rates. On the other hand, benign cysts should be handled conservatively with ultrasound follow-up or with minimally invasive surgery, while preserving fertility and avoiding unnecessary suffering. Transvaginal ultrasound assessment has a central role in the diagnostics of ovarian tumors as it has high accuracy, at least in the hands of ultrasound experts. There is currently a shortage of sonographers with enough experience though, as malignant tumors are relatively uncommon. Thus, there is a need to find alternatives to improve the diagnostics of ovarian tumors. In other medical fields, researchers have been able to develop automated imaging tools to improve diagnostic accuracy, for example when searching for breast cancer and bone fractures. Recent advances in computerized image analysis have been powered by deep neural networks (DNNs), which are computational versions mimicking the biological nervous system. Recently, researchers have developed and validated a DNN model (Ovry-Dx) to discriminate benign from malignant ovarian tumors based on 3077 ultrasound images from 758 patients. Ovry-Dx had a diagnostic accuracy comparable to human expert assessment. Further validating studies are needed to explore the generalizability and robustness of DNN models, and the clinical benefits in the hands of less experienced examiners. This study aims to compare the accuracy in differentiating benign from malignant masses using DNN models as compared to subjective assessment using pattern recognition or the IOTA-ADNEX model, by examiners of different levels of expertise.

Who can participate?
Women aged 15 years and over with a recently detected ovarian tumor, planned for either surgery or long time (at least 21 months) follow-up

What does the study involve?
Subjective assessment using pattern recognition and the IOTA-ADNEX model score will be compared to the DNN-model assessment. The histological outcome from surgery or long-time ultrasound follow-up (minimum 21 months) serves as the gold standard.

What are the possible benefits and risks of participating?
There are neither any benefits nor any risks as the DNN model outcome will not be shown to the examiner. The images will not be analysed by the DNN model until all patients have been examined. Therefore, participation will not affect the management of the patient.

Where is the study run from?
Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?
January 2020 to June 2026

Who is funding the study?
1. Swedish Research Council (Sweden)
2. Swedish Cancer Society (Sweden)
3. Stockholms Läns Landsting (Sweden)
4. Radiumhemmets Forskningsfonder (Sweden)

Who is the main contact?
Elisabeth Epstein, elisabeth.epstein@ki.se

# Contact information

### Type(s)
Principal Investigator

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Prof Elisabeth Epstein

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers

OV-AID-20230326

# Study information

### Scientific Title
Diagnostic accuracy of computerized ultrasound image analysis using deep neural network models as compared to subjective assessment using pattern recognition or IOTA-ADNEX model - a prospective multi-centre trial

### Acronym
OV-AID, Phase I

### Study objectives
The accuracy in differentiating benign from malignant masses using deep neural network (DNN) models is superior to subjective assessment using pattern recognition or the IOTA-ADNEX model, by non-expert examiners.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 02/02/2021, Etikprövningsmyndigheten (Sjukhusbacken 10, Uppsala, 750 02 Uppsala, Sweden; +46 (0)104750800; registrator@etikprovning.se), ref: 2020-07200, 2021-04549, 2021-06367-02, 2023-01834-02

### Study design
Prospective multicenter diagnostic accuracy study

### Primary study design
Observational

### Secondary study design
Cohort study

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

### Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

### Health condition(s) or problem(s) studied
Ovarian cancer

### Interventions
Current interventions as of 28/05/2024:
A prospective study including >700 patients with ovarian tumors, assessed by examiners with

varying expertise (at least 400 assessments by non-experts, and 300 by expert examiners). Subjective assessment using pattern recognition and the IOTA-ADNEX model score will be compared to DNN-model assessment. The histological outcome from surgery or long-time ultrasound follow-up (minimum 9 months, with scans after 3 and 6 months) serves as the gold standard. For every case: over four grayscale (at least two without callipers), two power Doppler still images and two video clips (with and without Doppler), should be collected.

Previous interventions:
A prospective study including >400 patients (at least 150 malignant) with ovarian tumors, assessed by examiners with varying expertise (at least 200 assessments by non-experts). Subjective assessment using pattern recognition and the IOTA-ADNEX model score will be compared to DNN-model assessment. The histological outcome from surgery or long-time ultrasound follow-up (minimum 21 months, with scans after 3, 6 and 12 months) serves as the gold standard. For every case: over four grayscale (at least two without callipers), two power Doppler still images and two video clips (with and without Doppler), should be collected.

### Intervention Type
Other

### Primary outcome measure
Diagnostic accuracy in differentiating benign from malignant ovarian tumors measured by comparing the outcomes from subjective assessment, IOTA-ADNEX model scoring and previously developed deep neural network (DNN) models at one timepoint

### Secondary outcome measures
Accuracy in differentiating benign from malignant ovarian tumors measured by comparing the outcomes from subjective assessment, IOTA-ADNEX model scoring and previously developed DNN models - stratified by user experience (expert examiners versus non-expert examiners) at one timepoint

### Overall study start date
01/01/2020

### Completion date
06/06/2026

## Eligibility

### Key inclusion criteria
1. Women aged ≥15 years
2. Newly detected ovarian tumor
3. Capable of understanding the study information and accepts participation

### Participant type(s)
Patient

### Age group
Mixed

### Lower age limit

15 Years

### Sex
Female

### Target number of participants
Minimum 700 participants, and at least 400 assessments are performed by non-experts.

### Key exclusion criteria
1. Aged <15 years
2. Patients who are not capable of understanding the study information or don't accept participation

### Date of first enrolment
01/03/2021

### Date of final enrolment
31/12/2025

## Locations

### Countries of recruitment
Czech Republic

Italy

Lithuania

Philippines

Poland

Spain

Sweden

### Study participating centre
**Södersjukhuset**
Department of Obstetrics and Gynecology
Stockholm
Sweden
11883

### Study participating centre
**Centrallasarettet Växjö**
Department of Obstetrics and Gynecology
Växsjö

Sweden
35234

**Study participating centre**
**Karolinska University Hospital, Huddinge**
Division of Gynecology and Reproduction
Huddinge
Sweden
14186

**Study participating centre**
**Aleris UltraGyn, Sabbatsbergs Hospital**
Sabbatsbergs Hospital
Stockholm
Sweden
11361

**Study participating centre**
**Uppsala University Hospital**
Department of Obstetrics and Gynecology
Uppsala
Sweden
75185

**Study participating centre**
**University Hospital Linköping**
Department of Obstetrics and Gynecology
Linköping
Sweden
58191

**Study participating centre**
**Skåne University Hospital**
Department of Obstetrics and Gynecology
Lund
Sweden
22242

**Study participating centre**

**Östra Hospital, Sahlgrenska University Hospital**
Department of Obstetrics and Gynecology
Gothenburg
Sweden
41685

**Study participating centre**
**Hallands Hospital**
Department of Obstetrics and Gynecology
Halmstad
Sweden
30233

**Study participating centre**
**Danderyds Hospital**
Department of Obstetrics and Gynecology
Danderyd
Sweden
18288

**Study participating centre**
**GynStockholm, Cevita Care**
Gynecology Clinic
Stockholm
Sweden
11281

**Study participating centre**
**Nyköpings Hospital**
Department of Obstetrics and Gynecology
Nyköping
Sweden
61139

**Study participating centre**
**NÄL Hospital Trollhättan**
Department of Obstetrics and Gynecology
Trollhättan
Sweden
46173

**Study participating centre**
**Örebro University Hospital**
Department of Obstetrics and Gynecology
Örebro
Sweden
70185

**Study participating centre**
**Skåne University Hospital**
Department of Obstetrics and Gynecology
Malmö
Sweden
21428

**Study participating centre**
**Karlstad Central Hospital**
Department of Obstetrics and Gynecology
Karlstad
Sweden
65230

**Study participating centre**
**Endogyn**
Stockholm
Sweden
131 31

**Study participating centre**
**Institute for the Care of Mother and Child**
Prague
Czech Republic
147 00

**Study participating centre**
**I.R.C.C.S. Burlo Garofolo Institute for Maternal and Child Health,**
Trieste
Italy
341 37

**Study participating centre**
**IRCCS San Gerardo Dei Tintori**
Department of Obstetrics and Gynecology
Monza
Italy
20900

**Study participating centre**
**University of Milano-Bicocca**
Department of Medicine and Surgery
Milan
Italy
20126

**Study participating centre**
**Fondazione Poliambulanza Istituto Ospedaliero**
Department of Obstetrics and Gynecology
Brescia
Italy
25124

**Study participating centre**
**Forlì and Faenza Hospitals**
Obstetrics and Gynecology Unit
Romagna
Italy
48018

**Study participating centre**
**Mater Olbia Hospital**
Gynecology and Breast Care Center
Olbia
Italy
07026

**Study participating centre**

**Medical University of Lublin**
Lublin
Poland
20059

**Study participating centre**
**Medical University of Silesia**
Katowice
Poland
40055

**Study participating centre**
**Rizal Medical Center**
Department of Obstetrics and Gynecology
Metro Manila
Philippines
1600

**Study participating centre**
**Hospital Universitario Dexeus**
Department of Obstetrics, Gynecology, and Reproduction
Barcelona
Spain
08028

**Study participating centre**
**Lithuanian University of Health Sciences**
Department of Obstetrics and Gynaecology
Kaunas
Lithuania
44307

# Sponsor information

**Organisation**
Karolinska Institute

**Sponsor details**

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+46 (0)8 524 800 00
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**Sponsor type**
University/education

**Website**
https://ki.se/kisos

**ROR**
https://ror.org/056d84691

# Funder(s)

**Funder type**
Government

**Funder Name**
Vetenskapsrådet

**Alternative Name(s)**
Swedish Research Council, VR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Sweden

**Funder Name**
Cancerfonden

**Alternative Name(s)**
Swedish Cancer Society

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Sweden

**Funder Name**
Stockholms Läns Landsting

**Alternative Name(s)**
Stockholm County Council

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Local government

**Location**
Sweden

**Funder Name**
Radiumhemmets Forskningsfonder

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer reviewed journal

**Intention to publish date**
30/06/2026

**Individual participant data (IPD) sharing plan**
Data from the analysis will be available upon request from Elisabeth Epstein (elisabeth.epstein@ki.se). Anonymized clinical data will be shared after publication; images and videos will not be available. All patients gave their informed consent to participate, but not specifically that data would be shared. All data have been anonymized only the PI of the study has access to the anonymization key.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| Protocol file | version 1 | 06/11/2023 | No | No |
| Protocol file | version 2 | 28/05/2024 | No | No |