ISRCTN88222986 https://doi.org/10.1186/ISRCTN88222986

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

Submission date
26/03/2023

Recruitment status
No longer recruiting

Registration date
01/04/2023

Overall study status
Completed

Last Edited
26/09/2025

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 9 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 9 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

Contact name
Prof Elisabeth Epstein

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Additional identifiers

Protocol serial number
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

Primary study design
Observational

Study design
Prospective multicenter diagnostic accuracy study

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
15 Years

Sex
Female

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
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20900

Study participating centre
University of Milano-Bicocca
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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

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

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