

# A clinical feasibility and performance study on the use of IntelligynAI for AI-driven support in ultrasound assessment of ovarian tumours

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|----------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>01/11/2024   | <b>Recruitment status</b><br>Recruiting                      | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>18/12/2024 | <b>Overall study status</b><br>Ongoing                       | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>18/12/2024       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

A critical shortage of expert ultrasound examiners has raised concerns of unnecessary interventions and delayed cancer diagnoses. AI support has the potential to reduce this burden and improve patient outcomes. Our team was the first to demonstrate that Deep Neural Network (DNN) models applied to ultrasound images can identify ovarian cancer in women with accuracy comparable to that of an experienced ultrasound expert (DOI: 10.1002/uog.23530). Recently, we confirmed in a large international multicentre validation study that these results are generalizable across different populations, ultrasound equipment, and examiners of varying levels of experience (Nature Medicine, accepted Oct 1st, 2024).

This study aims to evaluate a clinical workflow where examining physicians receive AI-driven support in real-time while performing an ultrasound examination of an ovarian lesion. Specifically, we want to assess:

- Whether the examining physician can produce and select ultrasound images suitable for AI analysis.
- How AI support impacts the physician’s workflow and work environment.
- How AI support influences the physician’s diagnostic confidence and patient management decisions.
- The alignment between the physician’s assessment, using AI support, and the final outcome from surgery or ultrasound follow-up over at least 9 months.

### Who can participate?

Women over 18 years of age with a newly detected ovarian lesion, who are examined at the Department of Obstetrics and Gynecology at Södersjukhuset, are eligible to participate.

### What does the study involve?

The study involves a clinical evaluating of an AI-driven support tool designed to assist in the ultrasound assessment of ovarian tumours.

What are the benefit and risk for the participants?

Scientific studies suggest that AI-driven decision support can contribute to faster and more accurate diagnostics, potentially avoiding unnecessary surgeries and enabling earlier cancer detection. However, for individual patients, there is a possibility that the AI model may provide an assessment that does not align with the final diagnosis determined by surgery. Importantly, it remains the attending physician's responsibility to determine the appropriate follow-up or treatment in consultation with the patient. The AI-driven decision support should be viewed solely as an advisory tool.

Where is the study run from?

The study is conducted by Karolinska Institutet in collaboration with Södersjukhuset, both located in Stockholm, Sweden.

When is the study starting and how long is the study expected to run for?

March 2024 to December 2026

Who is funding the study?

Karolinska Institutet, Stockholm Sweden is the sponsor of the study. The study is funded by Vinnova (the Swedish Agency for Innovation Systems) (Dnr 2024-01893).

Who is the main contact?

Professor Elisabeth Epstein, [elisabeth.epstein@ki.se](mailto:elisabeth.epstein@ki.se)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

### Protocol serial number

CIV-ID: CIV-24-02-046166

## Study information

## Scientific Title

A clinical feasibility and performance study on the use of IntelligynAI for computer-aided diagnostic support (CADs) in ultrasound assessment of ovarian tumours

## Acronym

IntelligynAI-FS

## Study objectives

The goal of this study is to evaluate the clinical feasibility and physician's perspectives on AI-driven support for the ultrasound assessment of ovarian tumours. Specifically, we aim to evaluate:

1. Workflow and Work Environment: How the AI support impacts the physician's workflow and work environment.
2. Confidence in Diagnosis: Whether the AI support increases the physician's confidence in diagnosing and managing the patient.
3. Image Quality for AI Analysis: The physician's ability to produce and select ultrasound images suitable for AI analysis.
4. Alignment with Final Outcomes: How well the physician's assessment, with AI support, aligns with the final outcomes from surgery or ultrasound follow-up over at least 9 months.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

1. Approved 29/05/2024, The Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 75002, Sweden; +46 10-475 08 00; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: Dnr 2024-03312-01
2. Approved 15/05/2024, The Swedish Medical Products Agency (Läkemedelsverket Box 26, Uppsala, 751 03, Sweden; +46 18-17 46 00; [registrator@lakemedelsverket.se](mailto:registrator@lakemedelsverket.se)), ref: 5.1-2024-28221

## Primary study design

Observational

## Study design

Single-centre regulatory study evaluating the feasibility and performance of an AI-driven diagnostic support device, IntelligynAI, for the assessment of ovarian tumours. The study integrates IntelligynAI into the clinical workflow for ultrasound evaluations.

## Study type(s)

Diagnostic, Other

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

Women with newly detected ovarian lesions, undergoing transvaginal ultrasound examination.

## Interventions

The study aims to assess a clinical workflow where examining physicians utilize AI-driven diagnostic support. During the ultrasound examination, selected images are sent to the IntelligynAI platform, which returns a report within seconds. This report includes an ovarian cancer risk prediction and a management proposal.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

IntelligynAI

**Primary outcome(s)**

Self-perceived confidence in the diagnosis and management provided by the examiner, in a study protocol, at the baseline ultrasound examination, self-perceived satisfaction and workload using AI support, through a doctor's questionnaire, at the end of the trial

**Key secondary outcome(s)**

1. Percentage of cases with adequately collected and selected images, through the review of patients' files at the end of the trial
2. Diagnostic accuracy: Alignment of the physician's assessment with AI support, through the study protocol filled out by the examiner at the time of the baseline ultrasound examination against final outcomes (from histology or ultrasound follow-up over at least 9 months), through the review of patient's files, at the end of the trial

**Completion date**

31/12/2026

**Eligibility****Key inclusion criteria**

Women with newly detected adnexal lesions (known for less than 4 months).

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Key exclusion criteria**

Individuals with a mental or psychological disability limiting their ability to give informed consent. Women with adnexal lesions known for more than 4 months. Women under 18 years of age.

**Date of first enrolment**

01/01/2025

**Date of final enrolment**

31/12/2026

**Locations****Countries of recruitment**

Sweden

**Study participating centre**

Södersjukhuset

Sjukhusbacken 10

Stockholm

Sweden

11883

**Sponsor information****Organisation**

Karolinska Institutet

**ROR**

<https://ror.org/056d84691>

**Funder(s)****Funder type**

Industry

**Funder Name**

VINNOVA

**Alternative Name(s)**

Swedish Governmental Agency for Innovation Systems, Vinnovase

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Sweden

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The datasets generated during this study, with the exception of the ultrasound images, will be published as a supplement to the publication of the study results.

**IPD sharing plan summary**

Published as a supplement to the results publication