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

Submission date
01/11/2024

Recruitment status
Recruiting

Registration date
18/12/2024

Overall study status
Ongoing

Last Edited
18/12/2024

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 erlier 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

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

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), 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), ref: 5.1-2024-28221

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.

Primary study design
Observational

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 asses 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, trough the review of patients files at the end of the trial
2. Diagnostic accuracy: Alignment of the physician’s assessment with AI support, trough 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 execption 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes