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Testing an ultrasound artificial intelligence model to help distinguish benign and malignant follicular thyroid tumours before surgery

Submission date 14/05/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/05/2026	**Overall study status** Ongoing	
Last Edited 15/05/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Follicular thyroid tumours include follicular thyroid adenoma, which is usually benign, and follicular thyroid carcinoma, which is malignant. These two conditions can look very similar on routine ultrasound scans, and it is often difficult to tell them apart before surgery. The final diagnosis usually depends on examination of the surgical specimen under the microscope. This study aims to test whether a new ultrasound artificial intelligence model called ProPRINT can help distinguish follicular thyroid carcinoma from follicular thyroid adenoma before surgery.

Who can participate?
Adult patients aged 18 years or older who have a thyroid nodule that is suspected to be a follicular thyroid tumour on routine ultrasound examination and if they undergo surgery as part of their usual clinical care. For the final analysis, only patients whose postoperative pathology confirms follicular thyroid carcinoma or follicular thyroid adenoma will be included.

What does the study involve?
Participants receive their usual clinical care. The study does not change biopsy, surgery, treatment, or follow-up decisions. Preoperative ultrasound images and relevant clinical and pathology information are collected for research. The ProPRINT model analyses the ultrasound images and gives a research prediction of whether the nodule is more likely to be benign or malignant. This result is used only for research validation and is not used to guide the participant's clinical management. The model result is compared with the final postoperative pathology diagnosis.

What are the possible benefits and risks of participating?
Participants may not receive a direct personal benefit because the model result does not change their treatment. The study may help improve future diagnosis of follicular thyroid tumours and may reduce unnecessary invasive procedures in future patients. The risks are minimal because no experimental treatment or additional invasive procedure is given as part of the study. The main risk is related to confidentiality of medical data, which will be reduced by using de-identified data and institutional data-protection procedures.

Where is the study run from?
The First Affiliated Hospital of Jinan University in China, China.

When is the study starting and how long is it expected to run for?
December 2025 to May 2026.

Who is funding the study?
The study is supported by research grants and institutional resources listed under the National Key Research and Development Program of China.

Who is the main contact?
Professor Shuixing Zhang, shui7515@126.com.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
A prospective multicentre observational diagnostic accuracy cohort study to validate Prototype-Guided Protein Representation INference from Thyroid Ultrasound (ProPRINT) for preoperative differentiation of follicular thyroid carcinoma and follicular thyroid adenoma

Acronym
ProPRINT prospective validation study

Study objectives
1. To prospectively validate the diagnostic accuracy of ProPRINT for preoperative differentiation of follicular thyroid carcinoma from follicular thyroid adenoma among patients with ultrasound-suspected follicular thyroid neoplasms.
2. To compare the diagnostic performance of ProPRINT with routine ultrasound-based assessment and ultrasound risk stratification systems, where available.
3. To evaluate the potential clinical utility of ProPRINT for simulated decision support, including its ability to reduce unnecessary invasive procedures while maintaining malignancy detection.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/05/2025, Medical Ethics Committee of Jinan University (Jinan University, No. 601 Huangpu Avenue West, Tianhe District, Guangzhou, 510632, China; +86 020-38688888; ohy@jnu.edu.cn), ref: JNUECKY-20251205-017

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Follicular thyroid neoplasms; preoperative differentiation of follicular thyroid carcinoma and follicular thyroid adenoma

Interventions
This is a prospective, multicentre, observational, non-interventional diagnostic accuracy cohort study. Patients with thyroid nodules suspected to be follicular thyroid neoplasms on routine preoperative ultrasound examination are prospectively enrolled. All participants continue to receive standard clinical care, including further diagnostic work-up and surgery when clinically indicated, according to the judgement of their treating clinicians and local practice. Preoperative ultrasound images and relevant clinical information are collected for research purposes. The locked ProPRINT model analyses the ultrasound images and generates a malignancy probability for each participant. The ProPRINT result is not used to determine biopsy, surgery, treatment, or follow-up decisions. After surgery, the final postoperative histopathological diagnosis is collected as the reference standard. Patients whose final diagnosis is not follicular thyroid carcinoma or follicular thyroid adenoma are excluded from the final diagnostic accuracy analysis. The diagnostic performance of ProPRINT is evaluated by comparing model predictions with final histopathology after completion of enrolment and data collection.

Intervention Type
Other

Primary outcome(s)
1. Diagnostic accuracy of ProPRINT for differentiating follicular thyroid carcinoma from follicular thyroid adenoma measured using area under the receiver operating characteristic curve (AUC) calculated using ProPRINT-predicted malignancy probabilities compared with the final postoperative histopathological diagnosis as the reference standard, at the completion of enrolment and availability of postoperative histopathological diagnosis for enrolled participants

Key secondary outcome(s))
1. Diagnostic accuracy of ProPRINT for distinguishing follicular thyroid carcinoma from follicular thyroid adenoma measured using the sensitivity, specificity, accuracy, positive predictive value, and negative predictive value calculated using standard diagnostic test statistics, with ProPRINT-

predicted malignancy classification compared against postoperative histopathological diagnosis as the reference standard at completion of enrolment and availability of postoperative histopathological diagnosis for enrolled participants

2. Clinical decision support performance of ProPRINT for simulated fine-needle aspiration recommendation measured using unnecessary biopsy rate, missed-malignancy rate, total biopsy recommendation rate, and number needed to biopsy calculated by applying predefined decision thresholds to ProPRINT predictions and comparator ultrasound risk stratification systems, using postoperative histopathological diagnosis as the reference standard at completion of enrolment and availability of postoperative histopathological diagnosis for enrolled participants

Completion date
20/05/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Patients with a thyroid nodule suspected to be a follicular thyroid neoplasm on routine preoperative ultrasound examination
3. Patients who undergo thyroid surgery as part of routine clinical care and have a final postoperative histopathological diagnosis
4. Patients whose final postoperative histopathology confirms follicular thyroid carcinoma or follicular thyroid adenoma
5. Patients with available preoperative thyroid ultrasound images of sufficient quality for model analysis
6. Patients with available essential clinical and pathological data required for diagnostic validation
7. Patients who provide written informed consent if required by the ethics committee and local regulations

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Final postoperative histopathological diagnosis other than follicular thyroid carcinoma or follicular thyroid adenoma.
2. History of thyroid intervention before the index ultrasound examination, including thyroid surgery, radiofrequency ablation, microwave ablation, ethanol ablation, or other local treatment.
3. Poor-quality preoperative ultrasound images that preclude reliable lesion identification or model analysis, including severe artefacts, incomplete lesion coverage, or inadequate resolution.
4. Missing essential clinical, ultrasound, or pathological data required for diagnostic validation.
5. Withdrawal of consent, if consent is required.

Date of first enrolment
05/12/2025

Date of final enrolment
15/05/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
Jinan University

ROR
https://ror.org/02xe5ns62

Funder(s)

Funder type

Funder Name
National Key Research and Development Program of China

Alternative Name(s)
, National Basic Research Program of China (973 Program), Special Fund for the National Key Research and Development Plan, China National Key Research and Development Plan Project, National Key Research and Development of China, National Key Research and Development Program, National Key R&D Program of China, National Key R&D Programmes of China, China's National Key R&D Programmes, National Basic Research Program of China, 973 Program, National Program on Key Basic Research Project (973 Program), National Plan on Key Basic Research and Development, National Basic Research Program, NKRDPC, NKPs

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available