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Artificial intelligence guidance systems for ultrasound may reduce the need for specialized ultrasound exams

Submission date 08/11/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/11/2025	**Overall study status** Completed	
Last Edited 14/11/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Deep vein thrombosis (DVT) is a term that describes blood clots (thrombi) that can form in the deep veins. The deep leg veins are commonly affected (such as the proximal veins: the femoral vein or the popliteal vein) or the deep veins of the pelvis. The standard approach to making a diagnosis involves an algorithm combining pre-test probability, a blood test called the D-dimer test, and the patient undergoing an ultrasound of the leg veins. Ultrasound is currently completed by a trained expert (e.g. sonographer or radiologist).

However, handheld ultrasound probes have recently become available and they have enabled ‘app-based’ ultrasonography to be performed. ThinkSono has developed a system (ThinkSono Guidance) allowing non-specialists to perform DVT ultrasound. Prior studies have established the effectiveness of this system. This study seeks to evaluate its real world clinical use in the emergency department.

Who can participate?
Patients aged 18 years and over, coming for a check to see if they have a DVT and have symptoms suggesting that they need an ultrasound scan

What does the study involve?
Participants undergo a compression ultrasound scan by a non-ultrasound trained staff member (e.g a nurse) using Thinksono Guidance, as well as a D-dimer blood test.

What are the possible benefits and risks of participating?
This study may allow participants to avoid waiting time for a sonographer-performed duplex ultrasound assessment. The results from this study will also improve knowledge of how Thinksono Guidance may be implemented to help detect blood clots accurately and quickly. Ultrasound is a very safe method of confirming a DVT or not, and is already used as standard care in hospitals. There are no additional risks of taking part.

Where is the study run from?
Attikon University Hospital (Greece)

When is the study starting and how long is it expected to run for?
April 2021 to May 2022

Who is funding the study?
ThinkSono GmbH (Germany)

Who is the main contact?
Sven Mischkewitz, hello@thinksono.com

Contact information

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Public, Scientific

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Additional identifiers

Study information

Scientific Title
Novel artificial intelligence guided non-expert compression ultrasound deep vein thrombosis diagnostic pathway may reduce vascular laboratory venous testing

Study objectives
ThinkSono Guidance is an artificial intelligence (AI) based software previously shown to aid non-experts without venous duplex ultrasound training in acquiring valid ultrasound images of venous compressions at the point of care that can be reviewed and interpreted by remote qualified clinicians. The present pilot study sought to evaluate its real world clinical use in the emergency department, sparing the need for sonographer-performed venous duplex ultrasound and potentially reducing patient waiting times.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/04/2021, Attikon University Hospital Institutional Review Board (Rimini, Chaidari, Athens, 124 62, Greece; +30 21 0583 1000; politis@attikonhospital.gr), ref: C24/07-04-2021

Primary study design
Interventional

Study design
Single-center non-randomized prospective trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Deep vein thrombosis (DVT)

Interventions
Patients with suspected DVT underwent an AI-guided proximal DVT compression examination by non-ultrasound-trained providers using ThinkSono Guidance and D-dimer testing. All patients assessed as compressible on ultrasound with negative D dimers were discharged. All other patients were sent for a venous duplex scan.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Thinksono Guidance

Primary outcome(s)
Thinksono Guidance image quality was measured using the American College of Emergency Physicians (ACEP) scale at the time of review

Key secondary outcome(s)
1. Sensitivity of AI-guided scans to detect proximal deep vein thrombosis (DVT) compared to duplex ultrasound, D dimer levels, or follow up, as appropriate, at the time of evaluation
2. Specificity of AI-guided scans to detect proximal DVT compared to duplex ultrasound, D dimer

levels, or follow up, as appropriate, at the time of evaluation
3. Negative Predictive Value (NPV) of AI-guided scans to detect proximal DVT compared to duplex ultrasound, D dimer levels, or follow up, as appropriate, at the time of evaluation
4. Positive Predictive Value (PPV) of AI-guided scans to detect proximal DVT compared to duplex ultrasound, D dimer levels, or follow up, as appropriate, at the time of evaluation
5. Proportion of patients discharged without the need for a duplex ultrasound scan (DUS), recorded from patient records at the time of discharge
6. Time to diagnosis, defined as the duration from initiation of the AI-guided scan to completion of on-call radiologist review, recorded from patient records during the analysis phase of the study

Completion date
07/05/2022

Eligibility

Key inclusion criteria
Patients suspected of having DVT

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
53

Key exclusion criteria
1. Patient withdrawal of consent
2. Incomplete scans

Date of first enrolment
10/05/2021

Date of final enrolment
05/05/2022

Locations

Countries of recruitment
Greece

Study participating centre
Attikon University Hospital
Rimini, Chaidari
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Greece
124 62

Sponsor information

Organisation
ThinkSono GmbH

Funder(s)

Funder type
Industry

Funder Name
ThinkSono GmbH

Results and Publications

Individual participant data (IPD) sharing plan
The anonymized ultrasound datasets generated during and/or analysed during the current study may be shared if a request is made to hello@thinksono.com. A statement about the use of the data must be made.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2025	10/11/2025	Yes	No