ISRCTN24293748 https://doi.org/10.1186/ISRCTN24293748

A pilot study to evaluate AI-assisted ultrasound software for the diagnosis of venous thrombosis

Submission date
11/05/2023

Recruitment status
No longer recruiting

Registration date
13/05/2023

Overall study status
Completed

Last Edited
27/05/2025

Condition category
Circulatory System

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

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 software (AutoDVT software) allowing non-specialists to perform DVT ultrasound, hoping it has the same accuracy for diagnosing DVT as the standard ultrasound. If this study has a positive outcome, it would mean that DVT could be diagnosed at the point of care by non-experts such as nurses, junior doctors, general practitioners and other healthcare staff. By diagnosing DVT early in the clinical pathway (for example, at GP practices), the technology could reduce emergency department admissions and free up specialists to focus on other clinical tasks. These improvements could also potentially reduce the financial burden of the DVT diagnostic service on healthcare systems.

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 two compression ultrasound scans. One is carried out by a non-radiology staff member (e.g. a nurse) using AI software to guide them and another ultrasound scan will be carried out as already scheduled by a sonographer or radiologist.

What are the possible benefits and risks of participating?
This study will not benefit participants directly in the short term but it may benefit patients having an ultrasound for a DVT in the future. The results from this study will improve knowledge of how software may be able to help diagnose blood clots accurately and quickly.

Ultrasound is a very safe method of confirming a DVT or not and is used already as standard care in hospitals. There are no risks of taking part. The scan does involve some pressing on the leg but if it is painful or participants want to stop they can let the researchers know.

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

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

Who is funding the study?
ThinkSono GmbH (Germany)

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

Contact information

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Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
v1.0.0

Study information

Scientific Title
A pilot study to evaluate AI-assisted ultrasound software for the diagnosis of venous thrombosis

Study objectives
This study will compare the standard protocol of lower extremity venous ultrasound to rule out venous thrombosis, as the recognised modality of choice, with ultrasound-assisted by artificial intelligence software (AutoDVT) combined with a remote assessment by a specialist radiologist.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/04/2021, Attikon University Hospital - Ethics Committee (1 Rimini Str, 12462 Chaidari, Greece; +30 210 5831692; greps@attikonhospital.gr), ref: ANT1N/ANGH, ED. 164/18-3-2021

Study design
Non-randomized prospective double-blind study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Proximal deep vein thrombosis

Interventions
Patients consented when scheduled for a DVT ultrasound exam with the radiology department.

An AI-assisted scan with the AutoDVT software is performed by a non-specialist (nurse). A follow-up gold-standard scan is performed by a local specialist (compression ultrasound), i.e. radiologist. That same-day follow-up scan represents the standard of care.

The images collected by the non-specialist are presented to a remote, qualified clinician who will evaluate image quality according to the quality scale of the American College of Emergency Physicians (ACEP) and consequently, if the image quality is sufficient, assesses whether the veins of the patient are compressible, incompressible or indeterminate.

This is a single-arm study. Every patient received the AI-guided scan and was followed up by a gold standard exam which represents the standard of care.

Nursing staff carried out the AI-guided ultrasound scan. They had no prior ultrasound experience at all. The remote qualified clinician assessing the images that have been collected by the AI-guided scan are qualified to diagnose DVT, i.e., radiologists.

The AI-guided scan was performed face-to-face. The images that have been presented to the remote qualified clinician are evaluated retrospectively via an internet platform. This remote qualified clinician did not see the patient.

The AI-guided scan was carried out in the rooms of the radiology department.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

Primary outcome measure
Sensitivity and specificity measured using AI-guided ultrasound and a local imaging specialist performing the gold-standard ultrasound exam at the same timepoint

Secondary outcome measures
Image quality of the AI-guided ultrasound measured by a remote qualified clinician according to the American College of Emergency Physicians (ACEP) scoring scale from 1 to 5 at one timepoint

Overall study start date
01/02/2021

Completion date
01/05/2022

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Suspicion of the presence of a deep vein thrombosis, indicating a compression ultrasound exam according to standard clinical practice
3. Capacity to consent to the study through the patients or the Legal Representative

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Inability to consent to the study or rejection through patients or the legal representative.
2. Pregnant for more than 12 weeks
3. D-dimer testing cannot be performed/patient is on anticoagulation
4. History of DVT in the symptomatic leg

Date of first enrolment
19/10/2021

Date of final enrolment
11/04/2022

Locations

Countries of recruitment
Greece

Study participating centre
University General Hospital "Attikon"
Rimini 1

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Sponsor information

Organisation
ThinkSono GmbH

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
ThinkSono GmbH

Results and Publications

Publication and dissemination plan
We plan to publish the study at a peer reviewed journal, potentially in combination with other study data. The writing of the publication and selection of the journal is currently ongoing.

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan

Due to patient confidentiality, no patient data will be shared. However, anonymised ultrasound data may be shared if a request is made be relevant authorities. This must be sent to hello@thinksono.com and a statement about the use of the data must be made.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2025	27/05/2025	Yes	No