ISRCTN24147434 https://doi.org/10.1186/ISRCTN24147434

Benefit of machine learning to diagnose deep vein thrombosis compared to the gold standard ultrasound

Submission date
11/05/2023

Recruitment status
No longer recruiting

Registration date
15/05/2023

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, GPs 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?
Helios Klinikum Emil von Behring, Klinik für Angiologie (Germany)

When is the study starting and how long is it expected to run for?
January 2022 to September 2022

Who is funding the study?
1. Imperial College London (UK)
2. Helios Klinikum Emil von Behring, Klinik für Angiologie (Germany)

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

Contact information

Type(s)
Scientific

Contact name
Mrs Kerstin Nothnagel

ORCID ID
https://orcid.org/0009-0004-5767-8346

Contact details
University of Bristol
Bristol Medical School
Room 1.10 (Desk 3)
Canynge Hall,
Clifton
Bristol
United Kingdom
BS8 2PN
+4915141406431
kerstin.nothnagel@bristol.ac.uk

Additional identifiers

Protocol serial number
V1.0

Study information

Scientific Title
Benefit of machine learning to diagnose deep vein thrombosis compared to the gold standard ultrasound

Study objectives
Measure the sensitivity and specificity of clinical decision-making based on images recorded by a non-specialist using AutoDVT AI-based software versus the ground truth produced by the local imaging specialist.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved on 15/03/2022, Ethics Committee of the Berlin Medical Association (Ethik-Kommission der Ärztekammer Berlin), (Working Committee Research II [Arbeitsausschuss Forschung II] Ärztekammer Berlin KdöR, Friedrichstr 16, 10969 Berlin, Germany; +49 30 408 06 26 01; ek@aekb.de), ref: Eth-07/21

Primary study design
Observational

Study design
Non-randomized prospective study

Study type(s)
Diagnostic

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

Interventions
Patient recruitment
Patients will consent when a DVT ultrasound exam is requested in the angiology 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. angiologist. 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 evaluated 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.

Study arms
Single-arm study. Every patient will receive an AI-guided scan which was followed up by a reference scan which represents the standard of care.

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

Modes of delivery
The AI-guided scan is performed face-to-face. The images that are presented to the remote,

qualified clinician will be evaluated retrospectively via an internet platform. This remote, qualified clinician will not see the patient. The AI-guided scan was carried out in the rooms of the angiology department.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
Sensitivity and specificity measured using the AI-guided ultrasound and a local imaging specialist performing the gold-standard ultrasound exam at one timepoint. The gold-standard exam is performed on the same day.

Key secondary outcome(s)
Image quality of the AI-guided ultrasound assessed by remote qualified clinicians, according to the American College of Emergency Physicians (ACEP) scoring scale from 1 to 5, at one timepoint

Completion date
01/09/2022

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Subject can consent and consent has been signed
3. Subject has symptoms of DVT and ultrasound is indicated

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
91

Key exclusion criteria
1. Below the age of 18 years old
2. No Wells score was calculated prior to the ultrasound
3. Distal DVT
4. Did not consent

Date of first enrolment
18/04/2022

Date of final enrolment
09/08/2022

Locations

Countries of recruitment
Germany

Study participating centre
Helios Emil von Behring Klinikum Zehlendorf
Walterhöferstrasse 11
14165 Berlin Germany
Berlin
Germany
14165

Sponsor information

Organisation
ThinkSono GmbH

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
ThinkSono GmbH

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from Sven Mischkewitz (hello@thinksono.com) if a request is made by relevant authorities and a statement about the use of the data has been made. Anonymised ultrasound data may be shared. No patient data will be shared due to patient confidentiality.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/01/2025	27/05/2025	Yes	No