

Comparing AutoDVT software with specialists in diagnosing blood clots

Submission date 11/05/2023	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/05/2023	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/05/2025	Condition category Circulatory System	☐ 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?

Helios Emil von Behring Klinikum Zehlendorf (Germany)

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

August 2021 to July 2022

Who is funding the study?

ThinkSono GmbH (Germany)

Who is the main contact?

Sven Mischkewitz, hello@thinksono.com

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

15.03.2021

Study information

Scientific Title

Evaluation of the diagnostic exclusion ability of the AutoDVT software for an algorithm-guided compression sonography in comparison to conventional compression sonography by experienced specialists

Study objectives

The evaluation of the remote qualified clinician is compared against the gold-standard ultrasound exam performed by a local specialist. The aim of this study is to judge the maturity of

the AutoDVT software for a powered follow-up study to show that adequate quality compression sequences can be reliably obtained by non-specialists and DVT can be excluded safely.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/08/2021, Ethikkommission Ärztekammer Sachsen-Anhalt (Am Kirchtor 9, 06108 Halle, Germany; +493453880936; bs-hal@aeksa.de), ref: 45/21

Primary study design

Interventional

Study design

Interventional non-randomised prospective double-blinded

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Proximal Deep Vein Thrombosis

Interventions

An AI-assisted scan with the AutoDVT software is performed by a non-specialist. A follow-up gold-standard scan is performed by a local specialist (compression ultrasound). 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.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

AutoDVT

Primary outcome(s)

Sensitivity and specificity compared between the AI-guided ultrasound and local imaging specialist performing the gold-standard ultrasound exam. 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. The overall proportion will be reported.

Completion date

14/07/2022

Eligibility

Key inclusion criteria

1. Age: at least 18 years old, of both sexes
2. Suspicion of the presence of a deep vein thrombosis, indicating a compression ultrasound exam according to standard clinical practice
3. Capacity to consent in the study through the patients or the legal Representative

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

26

Key exclusion criteria

Inability to the consent in the study or rejection through patients or the legal representative.

Date of first enrolment

08/10/2021

Date of final enrolment

27/05/2022

Locations

Countries of recruitment

Germany

Study participating centre

Klinikum Magdeburg

Birkenallee 34

Magdeburg

Germany

39130

Sponsor information

Organisation
ThinkSono GmbH

Funder(s)

Funder type
Industry

Funder Name
ThinkSono GmbH

Results and Publications

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		01/02/2024	27/05/2025	Yes	No