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# A pilot study to evaluate automatic deep vein thrombosis diagnostic software

**Submission date**
10/05/2021

**Registration date**
21/05/2021

**Last Edited**
27/05/2025

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Circulatory System

[X]  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) which it is hoped 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 the NHS.

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?
Nuffield Orthopaedic Centre (UK)

When is the study starting and how long is it expected to run for?
April 2021 to June 2024

Who is funding the study?
The Wellcome Trust via ThinkSono Ltd (UK)

Who is the main contact?
1. Chris Deane (trial manager, general queries), advent@nhsbt.nhs.uk
2. Fouad Al-Noor (general and technical queries), fouad@thinksono.com
3. Dr Nicola Curry (clinical queries), nicola.curry@ouh.nhs.uk

# Contact information

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# Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

285274

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

IRAS 285274

# Study information

**Scientific Title**

A multi-centre, prospective, double-blinded, pilot study evaluating artificial intelligence driven automatic detection of proximal deep vein thrombosis

**Acronym**

ADVENT

**Study objectives**

Deep vein thrombosis (DVT) is a term that describes a blood clot (thrombus) that can form in the deep veins. DVT commonly affects the proximal deep venous system of the legs: i.e. femoral vein, popliteal vein or the deep veins of the pelvis. The standard approach to making a diagnosis currently involves an algorithm combining pre-test probability, D-dimer testing, and compression ultrasonography (typically a two or three-point compression exam). This study will compare the gold standard two or three-point compression ultrasound exam with an automated

DVT scan guided by novel software (AutoDVT) and with AutoDVT with an additional review by a suitably qualified clinician with more than one year of experience diagnosing DVTs (e.g. sonographer or radiologist). The aim of the study is to estimate the sensitivity and specificity of the AutoDVT software and AutoDVT with an additional review by a suitably qualified clinician with more than 1 year of experience diagnosing DVTs (e.g. sonographer or radiologist) compared to two or three-point compression ultrasound exam.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 03/08/2021, East of Scotland Research Ethics Service REC 2 (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY, UK; +44 (0)1382 383871; tay.eosres@nhs.scot), ref: 21/ES/0070

## Study design
Multi-centre prospective double-blinded observational study

## Primary study design
Observational

## Study type(s)
Diagnostic

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

## Interventions
An AutoDVT software scan and remote radiology review are compared for accuracy with a clinical ultrasound scan. The study scan will not be used for diagnosis or to direct treatment.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
AutoDVT R1 Software

## Primary outcome(s)
1. Sensitivity of AutoDVT within a treatment algorithm for the detection of a proximal DVT by non-radiology trained staff relative to two- or three-point compression ultrasound, at initial scan and 7 days
2. Sensitivity of AutoDVT within a treatment algorithm for the detection of a proximal DVT by non-radiology trained staff and remote diagnosis by a suitably qualified clinician with more than 1 year of experience diagnosing DVTs (e.g. sonographer or radiologist) retrospectively relative to two- or three-point compression ultrasound, at initial scan and 7 days

## Key secondary outcome(s))

1. Specificity of AutoDVT relative to two- or three-point compression ultrasound, at initial scan and 7 days
2. Diagnostic image quality of AutoDVT US data (using ACEP image quality scale) across all initial and 7-day scans
3. Positive and negative predictive values of AutoDVT relative to two- or three-point compression ultrasound, at initial scan and 7 days
4. Imaging failure rates (with reasons) recorded by the software across all initial and 7-day scans
5. Numbers of discrepant results (AutoDVT vs ultrasound) recorded by comparing the software and clinical diagnoses at initial and 7-day scans
6. Interoperator variability of AutoDVT results assessed using a kappa statistic for 10% of initial scans
7. Interobserver agreement in DVT diagnosis and image quality score between 5 reviewers of each scan at initial scan and 7 days
8. Numbers of eligible patients not enrolled (with reasons) recorded by the research staff at enrolment
9. Safety: number of subsequent venous thromboembolic events and/or death related to venous thromboembolism (VTE) recorded by contacting the patient and/or General Practitioner at 3 months
10. Feasibility of recording of AutoDVT scans assessed using recruitment, user feedback and scans missed at initial scan and 7 days
11. Duration of AutoDVT scans recorded by the software at initial and 7-day scans
12. Number of indeterminate and repeat scans recorded by the software at initial and 7-day scans
13. Feedback from the research nurses on ease of use of the software (PSSUQ version 3 score and qualitative feedback) provided after they have done all scanning in the project

## Completion date
30/06/2024

# Eligibility

### Key inclusion criteria
1. The participant has the capacity to consent and consent is obtained
2. The participant is an adult (aged 18 years or older in the UK)
3. The participant has symptoms suggestive of a deep venous thrombosis (DVT)
4. The diagnostic DVT algorithm indicates that an ultrasound is needed

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex

All

## Key exclusion criteria
1. Pregnant women at 12 weeks or more gestation
2. A d-dimer cannot be performed (e.g. due to prior anticoagulation)
3. The participant is found to have a distal DVT during the US scan (retrospective exclusion)
4. The participant has had a previous radiologically confirmed DVT in the symptomatic leg

## Date of first enrolment
13/12/2021

## Date of final enrolment
31/03/2024

# Locations

## Countries of recruitment
United Kingdom

England

## Study participating centre
## Northern General Hospital
Herries Rd
Sheffield
United Kingdom
S5 7AU

## Study participating centre
## Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford
United Kingdom
OX3 7LD

## Study participating centre
## Stoke Mandeville Hospital
Mandeville Road
Aylesbury
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HP21 8AL

**Study participating centre**
**King's College Hospital**
Denmark Hill
London
United Kingdom
SE5 9RS


**Study participating centre**
**Princess Royal Hospital**
Farnborough Common,
Orpington.
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**Study participating centre**
**Leicester Royal Infirmary**
Infirmary Square
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**Study participating centre**
**Stepping Hill Hospital**
Stockport
United Kingdom
SK2 7JE


**Study participating centre**
**Cardiff & Vale University Health Board**
University Hospital of Wales
Heath Park
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CF14 4XW


# Sponsor information


## Organisation

Oxford University Hospitals NHS Trust

**ROR**
https://ror.org/03h2bh287

# Funder(s)

### Funder type
Research organisation

### Funder Name
Wellcome Trust

### Alternative Name(s)
Wellcome, WT

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
Access to the final dataset for additional analyses will be permitted with the agreement of the Trial Steering Committee after the end of the study. General participant-level data will be held by NHS Blood and Transplant for 10 years after the end of the study (contactable on ADVENT@nhsbt.nhs.uk). Data and images collected by the AutoDVT software will be held by Thinksono (contactable on hello@thinksono.com) indefinitely but only made available for non-commercial research use.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 15/09/2021 | 14/12/2021 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Other publications | | 01/03/2025 | 27/05/2025 | Yes | No |