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A pilot study to evaluate automatic deep vein thrombosis diagnostic software

Submission date
10/05/2021

Recruitment status
No longer recruiting

Registration date
21/05/2021

Overall study status
Completed

Last Edited
27/05/2025

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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Public

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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
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S5 7AU

Study participating centre
Nuffield Orthopaedic Centre
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Study participating centre
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Study participating centre
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Study participating centre
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University Hospital of Wales
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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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes