ISRCTN14795960 https://doi.org/10.1186/ISRCTN14795960

AI-guided deep vein thrombosis (DVT) diagnosis in primary care: protocol for cohort with qualitative assessment

Submission date	**Recruitment status**	[_] Prospectively registered
30/06/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/07/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/08/2024	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

In this study, we aim to investigate a new approach with the overarching goal of enhancing the detection of deep vein thrombosis (DVT). DVT is a medical condition characterised by the formation of blood clots within the deep veins, most commonly occurring in the legs. The current standard for diagnosing DVT involves utilising the Wells Score, a scoring system, in conjunction with a blood test called D-dimer, followed by an ultrasound scan (USS) administered by specialised healthcare professionals (HCP).

However, this study explores the potential of a transformative technology that could change this paradigm. A scenario has been envisioned in which ordinary individuals, without specialised ultrasound (US) training, could employ a smartphone application (app) to perform a DVT scan of the leg. This innovative app serves as a comprehensive guide, leading users through the steps necessary to conduct a leg US examination.

The significance of this research becomes apparent when considering the potential implications. If successful, this approach has the capacity to revolutionise DVT diagnosis, enabling patients to receive prompt assessments in the convenience of their primary care provider's office or even within their own homes. Such a development could substantially expedite the diagnosis process, offering enhanced convenience to patients and potentially reducing the number of emergency department (ED) visits. Additionally, this innovation holds the promise of alleviating some of the financial strain on healthcare systems like the National Health Service (NHS) by optimising DVT diagnostic services. In essence, this study seeks to pave the way for a future in which DVT diagnosis becomes more accessible, efficient, and financially sustainable for HCPs.

Who can participate?

GP Care DVT Clinic eligible patients who have the capacity to consent can participate in this study.

What does the study involve?

During an appointment at the GP Care DVT clinic, patients who agree to participate will be

consented and receive an additional ultrasound scan with the AI-guided handheld probe operated by the GP Care HCA. Participants are prompted to complete a participant satisfaction survey after the index and reference scan. A subgroup of 20 out of 562 participants will be invited for semi-structured interviews.

What are the possible benefits and risks of participating?
Benefit
- Participants may benefit from a quicker and more convenient assessment of their DVT risk.
- This method could reduce the need for immediate visits to specialised healthcare providers or emergency departments, saving time and potentially reducing healthcare costs.
- By participating, individuals contribute to research that could make DVT diagnosis more accessible and efficient in the future.
Risk
- As with any medical examination, there is a small risk of discomfort during the ultrasound scan.
- There is a potential risk that the app-guided scan might not be as accurate as a scan performed by a specialist, which could lead to either false reassurance or unnecessary concern. However, all app-guided scans will be reviewed by healthcare professionals to mitigate this risk.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
May 2023 to May 2026

Who is funding the study?
NHS Bristol, North Somerset and South Gloucestershire Integrated Care Board (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
332800

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 332800, CPMS 58280

Study information

Scientific Title
AI-guided point-of-care ultrasound for deep vein thrombosis diagnosis in primary care: protocol for a diagnostic accuracy and qualitative assessment study

Acronym
AID-DVT

Study objectives
Primary Hypothesis: AI-guided point-of-care ultrasound (POCUS) performed by non-specialists in primary care settings is as accurate as traditional ultrasound scans (USS) conducted by sonographers for the diagnosis of deep vein thrombosis (DVT).

Secondary Hypothesis: AI-guided POCUS for DVT diagnosis will be acceptable to patients and healthcare assistants (HCAs) in primary care settings, as measured by patient satisfaction surveys and semi-structured interviews.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/12/2023, London Bridge REC (2 Redman Place, Stratford, Stratford, E20 1JQ, United Kingdom; +44 2071048387; londonbridge.rec@hra.nhs.uk), ref: 23/PR/1242

Study design
Diagnostic cross-sectional study coupled with a qualitative evaluation

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

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

Interventions

AI-guided point-of-care ultrasound (POCUS) for the diagnosis of deep vein thrombosis (DVT) performed by healthcare assistants (HCAs) in primary care settings. This intervention is being compared to the traditional standard of care, which involves specialized ultrasound scans (USS) conducted by sonographers.

1. Enrolment:
- Participants with suspected DVT are enrolled at primary care DVT clinics.

2. Diagnostic Test Accuracy (DTA) Study:
- Participants undergo an AI-guided point-of-care ultrasound (POCUS) conducted by healthcare assistants (HCAs).
- This is followed by a standard ultrasound scan (USS) performed by sonographers.

3. Patient Satisfaction Survey (PSS):
- After completion of both the index (AI-guided POCUS) and reference (standard USS) scans, participants are prompted to complete a patient satisfaction survey.

4. Qualitative Semi-Structured Interviews:
- A subgroup of the participants will be invited to participate in semi-structured interviews to explore the acceptability of AI-guided DVT diagnosis in primary care.

Duration:
- Participants in the DTA will be in the study for 20-30 minutes.
- The subgroup of participants who agree to participate in semi-structured interviews will have their interviews within 1 to 3 weeks of participating in the DTA.
- There is no additional follow-up required after the qualitative interviews.

Intervention Type
Mixed

Primary outcome measure
Data collected during appointment:
1. Accuracy of HCA-reported AI-guided DVT diagnosis. Data Collected: Diagnosis of proximal DVT (yes/no). Method of Measurement: Comparison with reference standard of sonographer scan
2. Accuracy of AI-provided DVT diagnosis. Data Collected: Diagnosis of proximal DVT (yes/no). Method of Measurement: Comparison with reference standard of sonographer scan
3. Accuracy of remote specialist diagnosis using AI-guided acquired ultrasound images. Data Collected: Diagnosis of proximal DVT (yes/no). Method of Measurement: Comparison with reference standard of sonographer scan

Secondary outcome measures
Data collected after participant received index and reference scan:
1. Proportion of HCA-acquired images of adequate quality for renovate diagnosis. Data Collected image quality (adequate/inadequate according to ACEPO Score). Method of Measurement: Evaluation by 5 independent specialist (sonographer/ radiographer
2. Factors associated with inadequate image quality. Data Collected: Factors such as HCA experience, patient BMI, and machine settings. Method of Measurement: collected by CRN staff during patient recruitment at GPCare DVT Clinic
3. Patient satisfaction with AI-guided DVT diagnosis. Data Collected: Satisfaction score. Method of Measurement: Patient Satisfaction Survey

Qualitative Objectives:
1. Explore patient reservations, obstacles, and confidence in relation to AI-guided point-of-care US undertaking as a diagnostic scan for DVT
2. Explore the confidence of HCAs in the index scan
3. Explore the experience of HCAs in delivering the scan
Data Collected: Patient interviews, including demographic information (gender, age, postcode)
Method of Measurement Semi-structured interviews
Time-point 1-3 weeks post-scan

Overall study start date
01/05/2023

Completion date
01/05/2026

Eligibility

Key inclusion criteria
1. Eligible for GP Care DVT Services †1 flowchart
2. Participant has capacity to consent to study participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
105 Years

Sex
Both

Target number of participants
500

Total final enrolment
562

Key exclusion criteria
1. Unable to communicate in English (spoken or written) and there is no translator available.
2. For the qualitative study, patients who have a hearing impairment that would hinder the feasibility of an e-interview.

Date of first enrolment
26/02/2023

Date of final enrolment
14/06/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
GP Care DVT Clinic in NHS Bristol, North Somerset and South Gloucestershire
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Sponsor information

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Sponsor type
Research organisation

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ROR
https://ror.org/00340yn33

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
NHS Bristol, North Somerset And South Gloucestershire Integrated Care Board

Results and Publications

Publication and dissemination plan
The protocol of this study will be published in BJGP Open. Upon completion of the study, we aim to publish the findings in Nature. The data supporting the findings of this study will be made available upon reasonable request to the corresponding author, following publication of the results. This will include de-identified participant data, study protocols, and statistical analysis plans to ensure transparency and reproducibility of our research.

Intention to publish date
05/01/2026

Individual participant data (IPD) sharing plan
The dataset generated during the current study will be stored and available on the University of Bristol Data Repository.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		09/10/2023	04/07/2024	No	Yes
Protocol file		09/10/2023	04/07/2024	No	No