

# Hospice in-patient deep vein thrombosis detection study

<b>Submission date</b> 01/06/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/09/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-see-how-often-people-with-advanced-cancer-have-blood-clots-in-their-legs-hidden>

## Contact information

### Type(s)

Public

### Contact name

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### Contact details

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HU6 7RX

## Additional identifiers

### Protocol serial number

Version 1.0

## Study information

### Scientific Title

HIDDEN: Hospice In-patient Deep vein thrombosis Detection study

**Acronym**

HIDDen

**Study objectives**

Up to one in five cancer patients will develop blood clots in their veins known as deep vein thrombosis (DVT). A clot may break off from the DVT and travel to the lungs; known as a pulmonary embolism (PE). There are national treatment recommendations to prevent DVT in cancer patients admitted to hospital. However, it is not known whether these should apply to patients with advanced cancer admitted to specialist palliative care units (SPCU) such as hospices, as treatment may not alter how long patients have to live or improve symptoms and quality of life. It is not known if good effects outweigh side-effects of treatment (e.g. bleeding) in these patients. The aim of the HIDDen study is to find out how many cancer patients admitted to hospice units have a DVT via the use of a ultrasound scanner, at the hospice bedside, This study will determine how many cancer patients admitted to hospice units have DVTs and whether these cause problems and will result in a better understanding of how we should treat people with advanced cancer.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Health Research Authority, Yorkshire & The Humber - Leeds West Research Ethics Committee, 17/03/2016, ref: 16/YH/0045

**Study design**

Observational cohort study

**Primary study design**

Observational

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Femoral deep vein thrombosis (DVT) in cancer patients admitted to specialist palliative care units (SPCUs).

**Interventions**

An ultrasound scanner at the hospice bedside, will be used to scan patients' legs to test whether they have a DVT. Symptoms will be noted, and patients re-scanned a week later. Patients are also asked about their symptoms, their condition and medications.

Weekly assessments will be undertaken until participants are no longer fit for ongoing assessments, have died, or have been discharged, up to a maximum of 3 weeks' inpatient stay.

**Intervention Type**

Other

**Primary outcome(s)**

The prevalence of femoral DVT in cancer patients admitted to specialist palliative care unit (SPCU) measured by Doppler ultrasound

**Key secondary outcome(s)**

1. Incidence of developing a proximal lower limb DVT in patients with and without a diagnosis of cancer during admission to a SPCU
2. Prevalence of clinical symptoms and signs attributable to VTE (proximal lower limb DVT and PE) on admission to a SPCU
3. Incidence of clinical symptoms and signs attributable to VTE (proximal lower limb DVT and PE) during admission to a SPCU
4. Incidence of acute deterioration or sudden death in patients with a known DVT that could be attributed to clinical pulmonary emboli
5. Clinical characteristics associated with the presence or absence of proximal lower limb DVT
6. Association between use of anticoagulation and presence or absence of DVT on admission and during admission to a SPCU
7. Impact of proximal lower limb DVT on length of stay
8. Survival

**Completion date**

28/02/2018

**Eligibility**

**Key inclusion criteria**

1. Admitted to a participating SPCU
2. 18 years or older
3. Able to give fully informed written consent or an available nominated consultee
4. No physical limitations to performing the ultrasound assessment

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

343

**Key exclusion criteria**

1. Patients on other clinical trials will be considered on a case by case basis
2. Patients who are considered by the clinical team likely to die within 5 days
3. Where, in the case of a patient without mental capacity, the nominated consultee is too distressed to be approached regarding the study in the opinion of the clinical team
4. Patients unable to understand English well enough to provide informed consent or comply with study assessments

**Date of first enrolment**

06/06/2016

**Date of final enrolment**

10/10/2017

## **Locations**

**Countries of recruitment**

United Kingdom

England

Northern Ireland

Wales

**Study participating centre**

**Princess Alice Hospice**

W End Ln

Esher

United Kingdom

KT10 8NA

**Study participating centre**

**Northern Ireland Hospice**

Newtownabbey

United Kingdom

BT37 9RH

**Study participating centre**

**Marie Curie Hospice**

1A Kensington Rd

Belfast

United Kingdom

BT5 6NF

**Study participating centre**  
**Macmillan Unit**  
Antrim  
United Kingdom  
BT36 4TS

**Study participating centre**  
**Marie Curie Hospice**  
Bridgeman Rd  
Penarth  
Cardiff  
United Kingdom  
CF11 9LJ

## Sponsor information

**Organisation**  
University of Hull

**ROR**  
<https://ror.org/04nkhwh30>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research

## Results and Publications

**Individual participant data (IPD) sharing plan**  
Not provided at time of registration

**IPD sharing plan summary**  
Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/02/2019		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	exploratory substudy was the prevalence of DVT in patients with non-malignant palliative conditions	11/02/2022	06/09/2024	Yes	No
<a href="#">Participant information sheet</a>		07/07/2016	26/07/2016	No	Yes
<a href="#">Plain English results</a>				No	Yes
<a href="#">Protocol file</a>	version 4.0	22/09/2016	23/08/2022	No	No