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Hospice in-patient deep vein thrombosis detection study

Submission date	Recruitment status	[_] Prospectively registered
01/06/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/09/2024	Circulatory System	

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional files

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

Secondary outcome measures
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

Overall study start date
01/06/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
217 cancer patients

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
England

Northern Ireland

United Kingdom

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

Sponsor details
Cottingham Road
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England
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HU6 7RX

Sponsor type
University/education

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Results and Publications

Publication and dissemination plan
Peer reviewed journals and presentations at national and international conferences.

Intention to publish date
28/02/2019

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?
Plain English results				No	Yes
Participant information sheet		07/07/2016	26/07/2016	No	Yes
Results article	results	01/02/2019		Yes	No
Protocol file	version 4.0	22/09/2016	23/08/2022	No	No
HRA research summary			28/06/2023	No	No
Other publications	exploratory substudy was the prevalence of DVT in patients with non-malignant palliative conditions	11/02/2022	06/09/2024	Yes	No