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Anticoagulation Length in Cancer Associated Thrombosis (ALICAT)

Submission date 25/10/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/10/2012	**Overall study status** Completed	
Last Edited 23/07/2019	**Condition category** Circulatory System	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-heparin-blood-clots-caused-by-cancer-alicat

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2012-004117-14

ClinicalTrials.gov (NCT)
NCT01817257

Protocol serial number
EudraCT No. 2012-004117-14

Study information

Scientific Title
A feasibility study to inform the design of a randomised controlled trial to identify the most clinically and cost effective length of anticoagulation with low molecular weight heparin In the treatment of Cancer Associated Thrombosis

Acronym
ALICAT

Study objectives
The purpose of this study is to address a specific gap in the evidence base for the management of cancer associated Venous Thromboembolism (VTE) in patients with ongoing malignant disease. To address this evidence gap, a sufficiently powered randomised controlled trial (RCT) is needed, to gain information relating to the sample group, which entails a vulnerable adult population, of uncertain number, prognosis, and with uncertainty around willingness to recruitment or likely attrition. Therefore, a trial is proposed specifically to look at the feasibility of progression to a phase 3 RCT, the primary outcome of which would be to determine the proportion of recurrent symptomatic VTE in cancer patients receiving an additional six months LMWH.

The overarching aims of this study are to:
1. To identify practicalities of conducting a full RCT with regard to recruitment, retention and outcome measurement
2.To explore the barriers to progressing to a full RCT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
This is a two year, multicentre, mixed methods feasibility study including a randomised controlled two-arm interventional trial, a nested qualitative study, focus groups and a UK wide survey exercise.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer Associated Thrombosis

Interventions

Consenting patients will be randomised to one of two trial arms:
Arm A - Continue LMWH at treatment dose according to body weight for further six months.
Arm B - Discontinue LMWH once patient has received six months treatment following index VTE case.

Participants randomised to Arm A will have already received LMWH (Fragmin®), tinzaparin (Innohep®) or enoxaparin (Clexane®) at treatment dose for six months and should continue the same drug at the same dose for a further six months. No dose alterations are required unless clinically indicated.

Participants randomised to Arm B shall stop LMWH once a total of six months drug has been administered from the initial diagnosis of VTE.

Patients in both trial arms will be assessed at baseline, at week 12 of trial treatment and at week 26, i.e. the end of trial treatment. Patients in both trial arms will be given a diary booklet to record any other medications prescribed during the trial period. Quality of life questionnaires (EORTC QLQ-C30, EQ5D, and ESAS-r) will also be completed at these time points. Bleeding, VTE, and SAE events, and death and withdrawal, will be reportable up to 30 weeks after the date of randomisation.

Patients will not be followed up beyond the trial treatment period. However, if a participant is lost to follow up the WCTU will contact the participant's GP to obtain information on the participant's status. Participants will also have the option to consent to NHS IC Flagging for long term follow up of participant cause and date of death.

50-75 semi-structured interviews will be held with:

1. Patients who do not wish to continue with LMWH (non-consenters; 10-15)
2. Trial participants in the intervention arm (10-15);
3. Trial participants in the control arm (10-15);
4. Carers of trial participants (10-15);
5. Participants who withdraw from the study (10-15).

Focus groups with clinicians from oncology, haematology and primary care (two groups per setting; six groups in total) will explore:

1. Attitudes to recruiting to study to identify the challenges of progressing to a full RCT
2. Assessment of equipoise and acceptability of intervention
3. What evidence would be needed, if at all, to convince them to alter their practice in prescribing LMWH
4. Whether they would continue a patient on LMWH after six months
5. Views on the appropriate outcome measures for the RCT
6. Pathways they follow.

Data from the focus groups will be used to map/model the patient management pathways. A UK wide survey exercise will also be undertaken with relevant stakeholders from primary and secondary care. This will be in the form of a telephone/web survey and will allow a classification and enumeration of the models of care. This will also be triangulated with available documentary evidence on pathways of care.

The study will also identify key cost drivers to inform the design of a future definitive trial, which will include a cost utility study. Orders of magnitude of differences in costs and outcomes identified in the EQ-5D will help estimation of anticipated effect sizes for the full trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Number of eligible patients over 12 months
2. Number of recruited patients over 12 months (target recruitment rate of 30% of eligible patients)
3. Proportion of participants with recurrent VTEs during follow-up

Key secondary outcome(s))
1. Completion of trial protocol
2. Quality of life
3. Symptom assessment
4. Attitudes of clinicians and patients

Completion date
22/11/2014

Eligibility

Key inclusion criteria
1. Receiving low-molecular-weight heparin (LMWH) for treatment of Cancer Associated Thrombosis (CAT) for five months
2. Locally advanced or metastatic cancer
3. Able to self-administer LMWH, or have LMWH administered by a carer
4. Able to give informed consent
5. Age ≥18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Receiving drug other than LMWH for CAT
2. Contraindication to anticoagulation
2.1. Known allergies to LMWHs, heparin, sulfites or benzyl alcohol
2.2. Active major bleeding
2.3. History of heparin-induced thrombocytopenia
3. Confirmed recurrent VTE whilst receiving anticoagulation
4. Female patients who are pregnant

Date of first enrolment
20/12/2013

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cardiff University
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United Kingdom
CF14 4YS

Sponsor information

Organisation
Cardiff University (UK)

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2015		Yes	No
Protocol article	protocol	12/04/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes