

# Anticoagulation Length in Cancer Associated Thrombosis (ALICAT)

<b>Submission date</b> 25/10/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/07/2019	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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

### Contact name

Dr Simon Noble

### Contact details

Wales Cancer Trials Unit  
School of Medicine  
Cardiff University  
Neuadd Meirionydd  
Heath Park  
Cardiff  
United Kingdom  
CF14 4YS  
+44 (0)29 2068 7175  
[simon.noble@wales.nhs.uk](mailto:simon.noble@wales.nhs.uk)

## 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  $\geq$ 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**

Cardiff

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?
<a href="#">Results article</a>	results	01/10/2015		Yes	No
<a href="#">Protocol article</a>	protocol	12/04/2014		Yes	No