

# Anticoagulation of Calf Thrombosis (ACT): A Pilot Feasibility Study

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<b>Registration date</b> 03/12/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/07/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
781875

# Study information

## Scientific Title

The Anticoagulation of Calf Thrombosis (ACT) Study: a randomised controlled trial comparing standardised anticoagulation versus conservative therapy in the treatment of below knee deep vein thrombosis

## Acronym

ACT

## Study objectives

The treatment of a blood clot in the leg below the level of the knee is a long debated topic. There is ongoing discussion about whether to treat this condition actively with drugs to thin the blood (anticoagulants) or to simply 'watch and wait'. Both approaches are utilised at different hospitals in the North West.

Some hospitals 'watch and wait' only. They scan the leg 1 week after presentation, treating only if the clot gets bigger. Several research studies suggest this is as safe an approach as treating the clot. It also avoids exposing patients to the inherent risks of blood thinning drugs.

Other hospitals worry about the chance of the clot moving up the leg and rarely into the lungs. They practice treating all patients with anticoagulants to reduce these risks as much as possible. This also means that patients do not have to come back in a weeks time for another scan. Although some risk may be reduced by this approach, there is a potential for anticoagulant drugs to cause harm.

This research is trying to find out which approach is safest for patients. To find this out, we propose to randomly allocate patients with below knee blood clots to receive conservative treatment, (stocking supports and simple painkillers), or conservative treatment and anticoagulation. All patients will receive serial leg scans and be followed closely. Short-term assessment and long term follow up will occur.

If the trial shows a benefit from treating below knee clots, this will have a major impact on those hospitals which only scan above the knee, as many currently do. If the trial shows no benefit to treating the clots, many patients will be able to avoid the dangers of anticoagulation and further risk.

This feasibility trial will look to establish the percentage of recruitable patients from available cohort and feasibility of maintaining treatment allocation for three months.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The North West 7 Research Ethics Committee (REC) - GM Central approved on the 15th of November 2010 subject to a complete response to request for further information (ref: 10 /H1008/97)

## Study design

Prospective open label randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details below to request a patient information sheet

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

Calf thrombosis/below knee DVT

**Interventions**

Patients will be randomised to one of the following treatment groups

1. Group A: conservative treatment (TED stockings and simple analgaesia) and full-dose anticoagulation, initiated with Low Molecular Weight Heparin (LMWH) (dalteparin, dosage based on weight) then converted to oral anticoagulation with warfarin for a duration of 3 months total. Warfarin dosing to be based on International Normalized Ratio (INR) blood clotting measurements aiming for a target range of 2-3.
2. Group B: conservative treatment only

All patients will have vascular ultrasound scans at 7 days and 21 days to look for propagation or clot development, along with clinical review. All patients will be clinically followed for the three month duration of treatment. All patients will also be reviewed at two years regarding assessment for post-thrombotic leg syndrome.

**Intervention Type**

Other

**Phase**

Phase IV

**Primary outcome measure**

Combined incidence of thrombus propagation above knee or development of pulmonary embolism during the 3 months randomisation period

**Secondary outcome measures**

1. Incidence of major and minor bleeding episodes
2. Incidence of post thrombotic leg syndrome at 2 years using validated screening tool
3. Incidence of DVT recurrence at 2 years

**Overall study start date**

01/01/2011

**Completion date**

01/08/2012

## Eligibility

**Key inclusion criteria**

1. All ambulatory outpatients presenting to Manchester Royal Infirmary Emergency department diagnosed with below knee calf vein thrombosis by vascular ultrasound scan (USS)
2. Able to give informed consent
3. Aged 16-90

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100 for primary feasibility

**Key exclusion criteria**

1. Hospitalised patients
2. Patients on long-term anticoagulation
3. Associated proximal DVT or confirmed PE
4. Contraindication to anticoagulation (active bleeding, recent haemorrhagic CVA or upper GI bleed)
5. Other indication for immediate warfarinisation as per BSH guidelines: Prior confirmed and treated above knee DVT/PE, antiphospholipid syndrome, symptomatic inherited thrombophilia
6. Pregnancy
7. Chronic non propagating thrombus seen on prior USS
8. Previous enrolment to the ACT study and achievement of the primary outcome

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

01/08/2012

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Emergency Department**  
Manchester  
United Kingdom  
M13 9WL

## **Sponsor information**

### **Organisation**

Central Manchester NHS Foundation Trust (UK)

### **Sponsor details**

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### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.cmft.nhs.uk>

### **ROR**

<https://ror.org/00he80998>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

College of Emergency Medicine (UK)

### **Alternative Name(s)**

CEM

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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="#">Protocol article</a>	protocol	02/04/2012		Yes	No
<a href="#">Results article</a>	results	01/12/2014		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No