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

Submission date	Recruitment status	[X] Prospectively registered
27/11/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/12/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2014	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed

No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Emergency Department
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester NHS Foundation Trust (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

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	01/12/2014		Yes	No
Protocol article	protocol	02/04/2012		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes