ISRCTN86712308 https://doi.org/10.1186/ISRCTN86712308

SELECT-D: Anticoagulation therapy in SELECTeD cancer patients at risk of recurrence of venous thromboembolism

Submission date 24/04/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/04/2013	**Overall study status** Completed	
Last Edited 30/01/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-comparing-blood-thinning-injection-with-blood-thinning-tablet-for-people-with-cancer-who-have-blood-clot-select-d

Contact information

Type(s)
Scientific

Contact name
Miss Jaclyn Brown

Contact details
Clinical Trials Unit
Warwick Medical School
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL
-
J.Brown.10@warwick.ac.uk

Type(s)
Scientific

Contact name
Ms Catherine Hill

Contact details

Clinical Trials Unit
Warwick Medical School
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL
-
select-d@warwick.ac.uk

Type(s)
Scientific

Contact name
Prof Annie Young

Contact details
Clinical Trials Unit
Warwick Medical School
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL
-
annie.young@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number
2012-005589-37

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14296

Study information

Scientific Title
SELECT-D: Anticoagulation therapy in SELECTeD cancer patients at risk of recurrence of venous thromboembolism: a prospective, randomised, open label, multicentre pilot study

Acronym
SELECT-D

Study objectives

Prospective, randomised, open label, multicentre pilot study comparing dalteparin vs. rivoraxaban with a second placebo-controlled randomisation comparing the duration of anticoagulation therapy (6 months vs 12 months treatment) in Residual Vein Thrombosis [RVT] positive (+ve) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Coventry and Warwickshire, 08/02/2013, ref: 13/WM/0017

Study design
Randomised; Interventional; Design type: Treatment

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic/Disease: All Cancers/Misc Sites

Interventions
Dalteparin (Fragmin®, Pfizer), A low molecular weight heparin, the only licensed anticoagulant in the UK for the extended treatment and prevention of recurrence of VTE in cancer patients.

Rivaroxaban (Xarelto®, Bayer), An oral direct Factor Xa inhibitor, licensed for the treatment of DVT and the prevention of recurrence of DVT and PE in adult patients.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Dalteparin (Fragmin®, Pfizer), Rivaroxaban (Xarelto®, Bayer)

Primary outcome measure

VTE recurrence rates (including symptomatic VTE and incidental PE) calculated from the date of randomisation to the date of first VTE recurrence event.

Secondary outcome measures
1. Acceptability of the study assessed by the numbers randomised and screening logs for reasons for non-randomisation
2. Biomarker correlation
3. Compliance to treatment assessed by the frequency of withdrawals of therapy and duration of therapy
4. Feasibility of conducting an economic evaluation
5. Major bleeding and clinically relevant non-major bleeding. Time to major bleed or clinically relevant non-major bleed calculated from date of randomisation
6. Overall survival; calculated from the date of randomisation to the date of death from any cause
7. Patient experience measured using Anti-Clot Treatment Scale (ACTS)
8. Progression-free survival (adjuvant patients) calculated from the date of randomisation to the date of first progression or death from any cause
9. Quality of life measured using the EuroQol EQ-5D-5L questionnaire
10. Symptomatic VTE and incidental PE recurrence rates calculated from the date of randomisation to the date of first recurrence event
11. Tumour efficacy measured using the Response Evaluation Criteria In Solid Tumors (RECIST) assessment

Overall study start date
01/05/2013

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Patients with active cancer.
2. Patients with a primary presentation of an objectively confirmed venous thromboembolism (VTE) symptomatic deep venous thrombosis (DVT) or symptomatic or incidental pulmonary embolism (PE).
3. Eastern Cooperative Oncology Group (ECOG) Performance Status is 0, 1 or 2.
4. Age 18 years or over and written informed consent given.
5. Adequate haematological function (recommended levels haemoglobin (Hb) > 10g/dl, white cell count (WCC) > 2x10(9)/l, platelets > 100 x10(9)/l).
6. Adequate hepatic and renal function liver enzymes < x3 upper limit of normal (ULN) creatinine clearance > 30 ml per minute

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Planned Sample Size: 530; UK Sample Size: 530. Final recruitment 406.

Key exclusion criteria
Current exclusion criteria as of 31/08/2018:
1. Primary oesophageal or gastro-oesophageal cancer
2. Patients taking any anticoagulants.
3. Patients on more than 75 mg aspirin per day.
4. More than 72 hours pre-treatment with anticoagulant for this episode.
5. Clinically significant liver disease (e.g. acute hepatitis, chronic active hepatitis, or cirrhosis) or an alanine aminotransferase level that is equal to or greater than 3 times ULN range.
6. Bacterial endocarditis.
7. Active bleeding or a high risk of bleeding, contraindicating anticoagulant treatment.
8. Systolic blood pressure greater than 180 mm Hg or Diastolic blood pressure greater than 110 mm Hg.
9. Of childbearing potential (both male and female participants) without a combination of proper contraceptive measures.
10. Pregnant or breastfeeding.
11. Concomitant use of strong cytochrome P-450 3A4 inhibitors (e.g. human immunodeficiency virus protease inhibitors or systemic ketoconazole) or inducers (e.g. rifampicin, carbamazepine, or phenytoin) and p-glycoprotein inhibitors/ inducers.

Previous exclusion criteria:
1. Patients taking any anticoagulants.
2. Patients on more than 75 mg aspirin per day.
3. More than 72 hours pre-treatment with anticoagulant for this episode.
4. Clinically significant liver disease (e.g. acute hepatitis, chronic active hepatitis, or cirrhosis) or an alanine aminotransferase level that is equal to or greater than 3 times ULN range.
5. Bacterial endocarditis.
6. Active bleeding or a high risk of bleeding, contraindicating anticoagulant treatment.
7. Systolic blood pressure greater than 180 mm Hg or Diastolic blood pressure greater than 110 mm Hg.
8. Of childbearing potential (both male and female participants) without a combination of proper contraceptive measures.
9. Pregnant or breastfeeding.
10. Concomitant use of strong cytochrome P-450 3A4 inhibitors (e.g. human immunodeficiency virus protease inhibitors or systemic ketoconazole) or inducers (e.g. rifampicin, carbamazepine, or phenytoin) and p-glycoprotein inhibitors/ inducers.

Date of first enrolment
01/05/2013

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warwick Medical School
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

Sponsor details
Warwick Medical School
Coventry
England
United Kingdom
CV4 7AL

Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Industry

Funder Name
Bayer PLC

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

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?
Interim results article	interim results	10/07/2018		Yes	No
Results article	results	01/04/2020	30/01/2020	Yes	No
HRA research summary			28/06/2023	No	No