

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/04/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/01/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

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Scientific

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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) > 2x10⁹/l, platelets > 100 x10⁹/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.
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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