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A randomised phase III clinical trial investigating the effect of Fragmin® added to standard therapy In patients with lung cancer

Submission date 24/05/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/07/2005	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-to-find-out-if-dalteparin-can-improve-treatment-for-lung-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-002438-37

IRAS number

ClinicalTrials.gov number
NCT00519805

Secondary identifying numbers

2005-002438-37

Study information

Scientific Title
A randomised phase III clinical trial investigating the effect of FRAGMin® Added to standard Therapy In patients with lung Cancer

Acronym
FRAGMATIC

Study objectives
To assess the effect of adding six months of daily dalteparin (Fragmin) to standard treatment for patients with lung cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC for Wales, 08/08/2006, ref: 06/MRE09/29

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Lung cancer

Interventions
The trial is a multicentre randomised phase III trial. Patients are randomised to one of two groups with a 1:1 randomisation:
1. Control group: to receive anti-cancer treatment according to local practice
2. Intervention group: to receive anti-cancer treatment according to local practice plus once daily sub-cutaneous dalteparin (fragmin) for six months at a thromboprophylactic dose

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Dalteparin (fragmin)

Primary outcome measure
Overall survival

Secondary outcome measures
1. Venous thrombotic event (VTE) free survival
2. Serious Adverse Events (SAEs)
3. Metastasis-free survival
4. Toxicity
5. Quality of life
6. Levels of breathlessness
7. Anxiety and depression
8. Cost effectiveness and cost utility

Overall study start date
01/01/2006

Completion date
31/10/2011

Eligibility

Key inclusion criteria
Patients with histopathologically or cytologically confirmed primary lung cancer of any stage or histology.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2200

Total final enrolment
2202

Key exclusion criteria

1. Patients with other intrathoracic tumours (e.g. carcinoid, mesothelioma, lymphoma, lung metastases from another primary site)
2. Any previous illness or treatment likely to interfere with protocol treatment or comparisons
3. Known cerebral metastases
4. Haemoptysis of CTC Grade two (symptomatic haemoptysis requiring medical intervention) or above
5. Known bleeding diathesis
6. Known pregnancy or lactation
7. Known allergy to heparin
8. Platelet count lower than 100 x 10^9/l
9. Renal impairment with serum creatinine greater than 150 µmol/l
10. Patients who have received therapeutic anticoagulation in the last 12 months
11. Patients taking Ketorolac

Date of first enrolment
01/01/2006

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NICE
London
United Kingdom
WC1V 6NA

Sponsor information

Organisation
Velindre NHS Trust (UK)

Sponsor details
Unit 2, Charnwood Court
Parc Nantgarw
Cardiff
Wales
United Kingdom
CF15 7QW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05ntqkc30

Funder(s)

Funder type
Industry

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Pfizer UK

Alternative Name(s)
Pfizer Ltd, Pfizer Limited

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

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
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Protocol article	protocol	06/10/2009		Yes	No
Results article	results	10/02/2016		Yes	No
Results article	results	20/07/2016		Yes	No
Plain English results			26/10/2022	No	Yes