

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/07/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2005-002438-37

ClinicalTrials.gov (NCT)

NCT00519805

Protocol serial number

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

Study type(s)

Treatment

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(s)

Overall survival

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 $100 \times 10^9/l$
9. Renal impairment with serum creatinine greater than $150 \mu\text{mol/l}$
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

United Kingdom

England

Study participating centre

NICE

London

United Kingdom

WC1V 6NA

Sponsor information

Organisation

Velindre NHS Trust (UK)

ROR

<https://ror.org/05ntqkc30>

Funder(s)

Funder type

Industry

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), 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

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary**Study outputs**

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