ISRCTN25616445 https://doi.org/10.1186/ISRCTN25616445

Thromboembolic prophylaxis with enoxaparin in non-surgical cancer patients under systemic antineoplastic therapy

Submission date 26/11/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 04/04/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/08/2009	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Max E. Scheulen

Contact details
University of Duisburg-Essen
Hufelandstr. 55
Essen
Germany
45122

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Prospective, randomised, controlled open single-centre trial on thromboembolic prophylaxis with Enoxaparin in non-surgical cancer patients under systemic antineoplastic therapy

Acronym
VTETumor02

Study objectives
Can the use of Clexane® reduce the incidence of thrombosis and pulmonary embolism in cancer patients?

As of 20/02/2009 this record was updated to include an extended end date; the initial end date at the time of registration was 31/12/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Medical Faculty of the University of Duisburg-Essen gave approval on the 5th September 2007 (ref: 07/3375)

Study design
Open randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Thrombosis and pulmonary embolism in cancer patients

Interventions
Enoxaparin 40 mg subcutaneously daily for 24 weeks versus no therapy (because placebo injections are ethically not justifiable).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Clexane® (Enoxaparin)

Primary outcome(s)
Incidence of thrombosis and/or pulmonary embolism. Duration of follow-up: 24 weeks

Key secondary outcome(s))
1. Safety
2. Overall mortality

Duration of follow-up: 24 weeks

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Cancer patients
2. Inpatients
3. Treated with systemic antineoplastic therapy
4. Aged 18 - 85 years, either sex
5. One to three of the following factors given:
5.1. Prior thrombosis in medical history
5.2. Thrombosis in family
5.3. Fever
5.4. Elevated C-reactive protein (CRP)
6. Life expectancy greater than 24 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnancy (positive pregnancy test) or lactating
2. Simultaneous participation in another clinical trial
3. Women of child-bearing age without adequate contraception
4. Known heparin-induced thrombocytopenia (HIT) type II

Date of first enrolment
03/12/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Germany

Study participating centre
University of Duisburg-Essen
Essen
Germany
45122

Sponsor information

Organisation
University of Duisburg-Essen (Germany)

ROR
https://ror.org/04mz5ra38

Funder(s)

Funder type
Industry

Funder Name
Merck & Co., Inc. (USA)

Alternative Name(s)
Merck & Co., Inc., Merck & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration