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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/04/2008	**Overall study status** Completed	
Last Edited 03/08/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
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 measure
Incidence of thrombosis and/or pulmonary embolism. Duration of follow-up: 24 weeks

Secondary outcome measures
1. Safety
2. Overall mortality

Duration of follow-up: 24 weeks

Overall study start date
03/12/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

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)

Sponsor details
c/o Professor Max E. Scheulen
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45122

Sponsor type
University/education

Website
http://www.uni-duisburg-essen.de/index.shtml.en

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration