

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

Submission date 26/11/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/04/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/08/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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

Hufelandstr. 55

Essen

Germany

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