Prophylaxis of venous thromboembolism in patients with a fracture of the lower extremity being treated conservatively with a below-knee plaster cast.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Embolism and thrombosis
Study type	Interventional

Summary

ID

NL-OMON39940

Source
ToetsingOnline

Brief title
PROTECT

Condition

- Embolism and thrombosis

Synonym
pulmonary embolism, thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Glaxo Smith Kline;Rode Kruis Ziekenhuis,GlaxoSmithKline

Intervention

Keyword: fracture, plaster cast, profylaxis, thrombosis

Outcome measures

Primary outcome

The development of a deep-venous thombosis or pulmonary embolism.

Secondary outcome

The safety of nadroparin and fondaparinux.

Study description

Background summary

Although both trauma and immobilisation are two very well known risk factors in the development of deep vein thrombosis (DVT) no generally accepted strategy exists in dutch hospitals for patients being treated conservatively in a below-knee plaster for a fracture of a lower extremity.
Randomised controlled trials differ markedly in their conclusion with some trials advocating the use of LMWH and others advising against it. Also, patients being treated in a below-knee plaster cast have never been studied seperately. Therefore these conclusions are difficult to use for this specific group.
Both symptomatic and asymptomatic DVT can give rise to substantial morbidity and mortality, like post-thrombotic syndrome (PTS) and pulmonary embolism (PE). For years, the low-molecular-weight heparins have been considered to be the most effective and safest form of prevention of venous thromboembolism in patients requiring a relative short period of prophylaxis. However, a number of large recent studies have shown that fondaparinux is more effective in the prevention of DVT without increasing the risk of side-effects.

Study objective

The purpose of this study is to determine the need for thromboprofylaxis in patients being treated in a below-knee plaster cast after trauma of a lower extremity and if there is, to assess if both of the two tested prophylactic

treatments are suited for this indication.

Study design

A prospective, randomised, controlled, single blind, multi-centre trial.

Intervention

one group will receive 0,3 ml nadroparin s.c. once daily
one group will receive 0,5 ml fondaparinux s.c. once daily
one group recieves no intervention

Study burden and risks

When patients are assigned to a group with either nadroparin or fondaparinux they are instructed to inject themselves subcutaneaously once daily during the immobilisation period.
After removal of the plaster cast all patients will receive a colour duplex ultrasonography of the affected limb.

The risks are associated with the use of either fraxiparin or fondaparinux and include bleeding, allergic reactions, reversible eosinophilia, moderate thrombocytopenia, and elevation of liver enzymes. The chance to develop any of the above adverse outcomes is 1%.

Contacts

Public
VU Medisch Centrum

Boelelaan 1117
Amsterdam 1081 HZ
NL
Scientific
VU Medisch Centrum

Boelelaan 1117
Amsterdam 1081 HZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The study groups and the control group will consist of patients of 18 years or older with a nonsurgical fracture of the lower extremity requiring immobilisation in a below-knee plaster cast for a minimum of 4 weeks.

Exclusion criteria

Delay between injury and randomisation greater than three days
• Pregnancy/lactation
• Severe hepatic impairment
• Known hypersensitivity to fraxiparine or fondaparinux
• History of venous thromboembolism
• Documented congenital or acquired bleeding tendency/disorder(s)
• Previous or active bleeding from the digestive tract by peptic ulcer, tumours, hiatus hernia or diverticulosis
• Severe hypertension (systolic blood pressure above 180 mmHg or diastolic blood pressure above 110 mmHg)
• Haemorrhagic stroke within the previous two months
• Intraocular, spinal, and/or brain surgery within the previous twelve months
• Major surgery within the previous two months
• Treatment with LMWH or other anticoagulants
• Inability or refusal to give informed consent
• Inability to comply with the study-instructions

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-04-2009
Enrollment:	670
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Arixtra
Generic name:	Fondaparinux
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Fraxiparine
Generic name:	nadroparine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	11-12-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	12-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2008-004674-41-NL
CCMO	NL23109.094.08