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Prevention of portal vein thrombosis with anticoagulant therapy in patients with hepatic cirrhosis

Submission date 13/02/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/02/2012	**Overall study status** Completed	
Last Edited 18/10/2017	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Portal vein thrombosis (PVT) is blockage or narrowing of the portal vein (which brings blood from the intestines to the liver) by a blood clot. It is a frequent event in patients with advanced cirrhosis (scarring of the liver). When it occurs anticoagulant treatment improves the course of the disease. The aim of this study is to find out whether PVT can be prevented with the drug enoxaparin.

Who can participate?
Patients aged 18 and over with cirrhosis

What does the study involve?
Participants are randomly allocated to either be treated with enoxaparin daily for 1 year or to receive no treatment. The two groups are compared to see whether enoxaparin prevents PVT.

What are the possible benefits and risks of participating?
Enoxaparin is safe and effective at treating established PVT. Therefore, the benefits far outweigh the risks.

Where is the study run from?
University Hospital of Modena (Italy)

When is the study starting and how long is it expected to run for?
April 2008 to August 2012

Who is funding the study?
University Hospital of Modena (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2007-007890-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EudraCT Number: 2007-007890-22

Study information

Scientific Title
Prevention of portal vein thrombosis with anticoagulant therapy in patients with hepatic cirrhosis: a randomised controlled trial

Study objectives
Portal vein thrombosis (PVT) in patients with advanced cirrhosis may be prevented by prophylactic doses of enoxaparin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee Modena, 15/10/2007, ref: AOMODEN_*IV_2007_006

Study design
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 to request a patient information sheet

Health condition(s) or problem(s) studied
Advanced stage cirrhosis

Interventions
Experimental arm: Enoxaparin (Sanofi Aventis, Milan) subcutaneously at a dose of 4000 IU/day for 1 year.
Control arm: No treatment.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Prevention of portal or mesenteric vein thrombosis

Secondary outcome measures
1. Occurrence or recurrence of liver decompensation, defined as development of ascites, PSE, portal hypertensive bleeding, spontaneous bacterial peritonitis, or systemic infection
2. Overall and transplant-free survival

Overall study start date
01/04/2008

Completion date
30/08/2012

Eligibility

Key inclusion criteria
1. Age ≥18 years old
2. Cirrhosis of any etiology
3. Child-Pugh score between B7 to C10

3. No evidence of PVT or spleno-mesenteric thrombosis by ultrasound evaluation and angio-CT, hepatic, renal and coagulative evaluation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Age > 75 years
2. Ascites or porto-systemic encephalopathy (PSE) at time of enrollment or during the previous 3 months
3. History of gastrointestinal bleeding, hepatocellular carcinoma, other intra/extra-hepatic cancers, or thromboembolic disease
4. Ongoing anticoagulation, antiaggregation, or antiphospholipid antibody treatmen
5. Pregnancy or breastfeeding
6. F2 varices with red whale marks or F3 varices unless ligated
7. Platelet count < 10.000/mmc
8. Evidence of paroxysmal nocturnal hemoglobinuria (based on CD 55-CD 59 flow-cytometry); or
9. Human immunodeficiency virus (HIV) infection

Date of first enrolment
01/04/2008

Date of final enrolment
30/08/2012

Locations

Countries of recruitment
Italy

Study participating centre
University Hospital of Modena (Azienda Ospedaliero-Universitaria di Modena) (Italy)
Modena
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Sponsor information

Organisation
University Hospital of Modena (Azienda Ospedaliero-Universitaria di Modena) (Italy)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.policlinico.mo.it/Sito/

ROR
https://ror.org/01hmmsr16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of Modena (Azienda Ospedaliero-Universitaria di Modena) (Italy)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2012		Yes	No