

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
Registration date 21/02/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/10/2017	Condition category Digestive System	☐ Individual participant data

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?

Prof. Erica Villa
erica.villa@unimore.it

Contact information

Type(s)

Scientific

Contact name

Prof Erica Villa

Contact details

Via del Pozzo 71

Modena

Italy

41124

-

erica.villa@unimore.it

Additional identifiers

Clinical Trials Information System (CTIS)

2007-007890-22

Protocol serial number

EudraCT Number:

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

Prevention of portal or mesenteric vein thrombosis

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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 treatment
5. Pregnancy or breastfeeding
6. F2 varices with red whale marks or F3 varices unless ligated
7. Platelet count < 10.000/mm³
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

Italy

41124

Sponsor information**Organisation**

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

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

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