ISRCTN12504151 https://doi.org/10.1186/ISRCTN12504151

Warfarin anticoagulation for liver fibrosis in patients transplanted for hepatitis C virus infection

Submission date	Recruitment status	[_] Prospectively registered
17/04/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/09/2023	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Mark Thursz

Contact details
Hepatology Section
Imperial College St Mary's Campus
Norfolk Place
London
United Kingdom
W2 1NY
+44 (0)20 7594 3851 or 7886 1903
m.thursz@imperial.ac.uk

Additional identifiers

Protocol serial number
G0701716

Study information

Scientific Title

Warfarin Anticoagulation for liver Fibrosis in patients Transplanted for hepatitis C virus infection

Acronym
WAFT-C

Study objectives
Anticoagulation reduces the rate of liver fibrosis in patients who have received a liver transplant for hepatitis C related disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Royal Free Hospital and Medical School Research Ethics Committee, 20/06/2007, ref: 07/Q0501/79

Primary study design
Interventional

Study design
Randomised controlled open-label trial (randomisation is stratified by gender and centre)

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prevention of liver fibrosis in patients who have received a liver transplant as a result of hepatitis C virus (HCV) infection

Interventions
Warfarin (anticoagulation) for a duration of 2 years at a dose to maintain the international normalised ratio (INR) at 2 - 3. The warfarin will be taken orally on a daily basis. The control group will receive standard post-transplant care only. The follow-up duration of the trial is the duration of the intervention i.e., 2 years, after which patients will be followed up as per routine clinical care in their respective liver transplant clinics.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Stage of liver fibrosis at end of treatment period (2 years)

Key secondary outcome(s)

1. Number of activated hepatic stellate cells per high power field on liver biopsy
2. Non-invasive measures of liver fibrosis

Completion date
01/07/2012

Eligibility

Key inclusion criteria
1. Hepatitis C virus (HCV) infection
2. Aged over 17 years, either sex
3. Liver transplant within previous 4 months
4. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
17 Years

Sex
All

Key exclusion criteria
1. Patients requiring anticoagulation for existing clinical indications
2. Standard contraindications to anticoagulation (active peptic ulcer disease, past history of haemorrhagic stroke, thrombocytopaenia (platelets count less than 90 x10^9/L)
3. Large oesophageal varices persisting post-transplant
4. Cerebrovascular abnormalities on pre-transplant computed tomography (CT) scan
5. Human immunodeficiency virus (HIV) antibody positive

Date of first enrolment
01/07/2007

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Imperial College London (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research organisation

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Abstract results	1-year interim results presented at the International Liver Congress	23/04/2015	05/09/2023	No	No
Thesis results	1-year interim results	01/11/2011	05/09/2023	No	No