

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

Submission date 17/04/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 31/10/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/09/2023	Condition category Digestive System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Study design

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

Primary study design

Interventional

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 $90 \times 10^9/L$)
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