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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
Stage of liver fibrosis at end of treatment period (2 years)

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

Overall study start date
01/07/2007

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

Age group
Adult

Lower age limit
17 Years

Sex
Both

Target number of participants
90

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
England

United Kingdom

Study participating centre
Imperial College
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Clinical Research Office
G02, Sir Alexander Fleming Building
South Kensington
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

Website
http://www3.imperial.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
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