

A multi-centre prospective controlled trial comparing calcineurin inhibitor monotherapy with sirolimus monotherapy in hepatitis C infected patients with hepatic fibrosis following liver transplantation

Submission date 12/05/2010	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/01/2019	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

7761

Study information

Scientific Title

A multi-centre prospective controlled trial comparing calcineurin inhibitor monotherapy with sirolimus monotherapy in hepatitis C infected patients with hepatic fibrosis following liver transplantation

Acronym

Sirolimus and Hepatitis C following Liver Transplantation V1

Study objectives

We hypothesise that in patients who have had liver transplants for Hepatitis C and have damage in their liver graft secondary to Hepatitis C will have this damage slowed by changing from their standard immunosuppressive regime to the drug sirolimus. This study will test this hypothesis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved (ref: 03/H0304/92)

Study design

Multicentre randomised observational treatment cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Hepatology

Interventions

Sirolimus, Change from Standard Immunosuppression to Sirolimus

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Sirolimus

Primary outcome measure

Liver Biopsy Fibrosis Score

Secondary outcome measures

1. Diabetic status
2. Renal function
3. Cardiovascular risk index

Overall study start date

01/05/2010

Completion date

01/12/2013

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Planned sample size: 120

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/05/2010

Date of final enrolment

01/12/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Cambridge

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Addenbrooke's Hospital (UK)

Sponsor details

Cambridge Cancer Trials Office

Oncology Centre, Box No 193

Hills Road

Cambridge

England

United Kingdom

CB2 2QQ

Sponsor type

Hospital/treatment centre

Website

<http://www.oncology.cam.ac.uk/research/themes/cctc.html>

ROR

<https://ror.org/055vbx86>

Funder(s)

Funder type

Industry

Funder Name

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