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

Submission date 12/05/2010	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 12/05/2010	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 18/01/2019	**Condition category** Digestive System	[ ] Individual participant data [ ] 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 monthotherapy 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 Immunosupression 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/055vbxf86

Funder(s)

Funder type
Industry

Funder Name

Wyeth Pharmaceuticals (UK)

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