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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/05/2010	**Overall study status** Stopped	
Last Edited 18/01/2019	**Condition category** Digestive System	

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
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

Study type(s)
Treatment

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(s)
Liver Biopsy Fibrosis Score

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre

University of Cambridge
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Addenbrooke's Hospital (UK)

ROR
https://ror.org/055vbxf86

Funder(s)

Funder type
Industry

Funder Name
Wyeth Pharmaceuticals (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration