# 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	Recruitment status	Prospectively registered
12/05/2010	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/05/2010	Stopped	Results
Last Edited	Condition category	Individual participant data
18/01/2019	Digestive System	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

Dr Arun Shankar

### Contact details

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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