Backflow hepatic arterial flush of liver graft by hepatic vein occlusion in living donor liver tranplantation

Submission date	Recruitment status	Prospectively registered
01/10/2010	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
19/10/2010	Completed	Results
Last Edited	Condition category	Individual participant data
19/10/2010	Surgery	[] Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

97-04-10

Study information

Scientific Title

Retrograde arterial flush of the liver graft in living donor liver transplantation: a prospective randomised study

Study objectives

Formal arterial flush of graft during recovery procedures in living donor liver transplantation (LDLT) is usually not performed, so the beneficial effects of arterial flush in LDLT is not well known. The aim of this study was to evaluate the effects of arterial flush of graft in LDLT by using retrograde arterial flush (RGAF) of liver graft which prevented the injury of arterial intima.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional review board of Veterans General Hospital, Taipei, approved on the 16th May 2008

Study design

Interventional single-blind single centre randomised study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Liver transplantation

Interventions

After complete parenchymal dissection of the donor liver and cutting the bile duct, intravenous heparin (2000 U) was given to the donor. Two minutes after heparin injection, the graft was quickly removed into the iced basin with transient warm ischaemia which was always less than 5 minutes.

In the non-RGAF group, the graft was flushed via the portal vein with 3 times the graft weight (g) of chilled histidine-tryptophan-ketoglutarate (HTK) solution under gravity at a height of 1 metre in the back table. The bile duct and hepatic artery was flushed gently by 5 cc HTK solution using a 24 gauge catheter.

In the RGAF group, the graft was first flushed via the portal vein with 2 times the graft weight (g) of chilled HTK solution as non-RGAF group and then the hepatic vein(s) is (are) clamped by delicate Pott's vascular clamp(s) and the graft was flushed via the portal vein with 500 cc chilled HTK solution (200 cc for left lateral segment). Then the vascular clamp(s) was (were) released.

The procedure of retrograde flush was repeated until the effluent from hepatic vein became clear. The bile duct was flushed gently by 5 cc HTK solution using a 24 gauge catheter. For both groups, the reconstructions of the vessels and bile ducts of the graft were performed thereafter if necessary.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

- 1. Intra-operative haemodynamic changes
- 2. One-month post-transplantational liver function tests
- 3. Occurrence rates of acute cellular rejection within first month after transplantation
- 4. Immediate preservation injuries of the graft livers by retrograde arterial perfusion

Secondary outcome measures

- 1. Rates of vascular and biliary complications
- 2. Length of post-operative hospital stay
- 3. Graft and patient survival rates

Overall study start date

20/06/2006

Completion date

10/10/2010

Eligibility

Key inclusion criteria

- 1. Donors' ages range from 18 to 65 years
- 2. Recipients' aged under 70 years according to the law in Taiwan

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

- 1. Retransplantation
- 2. Small- or large-sized grafts (graft-versus-recipient weight ratio, GRWR less than 0.8%, or greater than 5%)
- 3. Recipients with complete portal vein thrombosis
- 4. Recipients needing renal replacement therapy before LDT

Date of first enrolment

20/06/2006

Date of final enrolment

10/10/2010

Locations

Countries of recruitment

Taiwan

Study participating centre No. 201, Sec. 2, Shih-Pai Rd.

Taipei Taiwan 112

Sponsor information

Organisation

Taipei Veterans General Hospital (Taiwan)

Sponsor details

c/o Chen-Hsen Lee Chairman Institutional Review Board No. 201, Sec. 2, Shih-Pai Rd. Taipei Taiwan 112

Sponsor type

Hospital/treatment centre

Website

http://homepage.vghtpe.gov.tw/~mre/goodexp/content.htm

ROR

https://ror.org/03ymy8z76

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Taipei Veterans General Hospital (Taiwan) - research grant (ref: TVGH 98, S22-004)

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