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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

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional single-blind single centre randomised study

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
1. Rates of vascular and biliary complications
2. Length of post-operative hospital stay
3. Graft and patient survival rates

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
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Sponsor information

Organisation
Taipei Veterans General Hospital (Taiwan)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration