Hand-assisted laparoscopic donor nephrectomy of the right or left kidney.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25262

Source
Nationaal Trial Register

Brief title
LAPNIER STUDY

Health condition

Kidney transplantation, laparoscopy, minimally invasive surgical procedures, donor nephrectomy.

Sponsors and support

Primary sponsor: sponsor Academic Medical Center (AMC)
address P.O. Box 22660
postal code 1100 DD
city Amsterdam
country The Netherlands
phone +31 (0)20 5669111

Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Operation time.

Secondary outcome

1. Donor morbidity;

2. Warm ischaemia time;

3. Delayed graft function;

4. Urological complications;

5. Graft survival;

6. Quality of life.

Study description

Background summary

The number of living donor transplantations has increased during the past 20 years due to the
shortage of deceased kidney donors and an increased number of patients on the waiting list for renal transplantation. Living donor kidney transplantation is superior to deceased donor kidney transplantation because of the better patient and graft survival rates, better cost-effectiveness and improved quality of life (QoL) of the recipient (1,2). Open living donor nephrectomy is associated with disincentives including long hospital stay, prolonged postoperative pain, cosmetic problems and slow convalescence. These disincentives might be a drawback for potential donors to donate a kidney. With the advent of laparoscopic living donor nephrectomy a reduction in hospital stay, less postoperative analgesic requirements, improved cosmetics, and an earlier return to normal daily activities have been reported (3). There is an ongoing discussion whether the right or the left kidney donor nephrectomy is to be preferred. Most centers prefer to use the left kidney for live kidney donation because of the longer renal vein, which is advantageous during the implantation. However, some surgeons prefer the right kidney because it is easier to recover than the left kidney and the risk of spleen laceration is decreased (4). A recent study demonstrate the negative effect of longstanding pneumoperitoneum on kidney function. Reduction of operation time with maintenance of the beneficial effect of the minimal invasive aspect of the laparoscopic donor nephrectomy is essential(5). There are no prospective studies comparing the outcome of left sided versus right sided laparoscopic donor nephrectomy in terms of operating time.

Therefore a prospective single-center randomized trial was conducted performing either a left or a right sided hand-assisted laparoscopic donor nephrectomy.

Study objective

The hypothesis was that donors who underwent a right sided HALDN would have a shorter operation time.

Study design

N/A

Intervention

Specific preoperative donor evaluation included blood and urine examination, angiography, pyelography and renal scintigraphy.

In case of bilateral multiple arteries they were only included in the study if both kidneys were judged transplantable by the surgeon.

The hand-assisted laparoscopic donor nephrectomy (HALDN) is done transperitoneally.

After open dissection of the distal ureter and gonadal vein through a 7-8 cm Pfannenstiel incision the non dominant operators' hand is introduced through a handport and two 10-12 mm trocars are placed. The insufflation pressure was maximally 12 mmHg. The right or left colon was then mobilized. After transecting the ureter distally, the renal artery is transected with metal clips, while an endoscopic stapler is used to transect the renal vein. The kidney is extracted through the Pfannenstiel incision and cold flushed and preserved with University of Wisconsin solution (UW).

Postoperatively, all patients are treated equally with regard to feeding, pain regulation, mobilization and postoperative care.

Contacts

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Eligibility criteria

Inclusion criteria

1. Donors with age above eighteen years;

2. An identical kidney with regard to renal vascular anatomy;

3. Renal function and urinary tract;

4. Written informed consent.

Exclusion criteria

1. Unilateral multiple renal arteries.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2002

Enrollment:	60
Type:	Actual

Ethics review

Positive opinion Date:	24-07-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL998
NTR-old	NTR1027
Other	:
ISRCTN	ISRCTN90285720

Study results

Summary results

Maartense S, Idu M, Bemelman FJ, Balm R, Surachno S, Bemelman WA.
Hand-assisted laparoscopic live donor nephrectomy.
Br J Surg. 2004 Mar;91(3):344-8.
Lind MY, Hazebroek EJ, Hop WC, Weimar W, Jaap Bonjer H, IJzermans JN. Right-sided laparoscopic live-donor nephrectomy: is reluctance still justified? Transplantation. 2002; 74:1045.

Buell JF, Edye M, Johnson M, et al. Are concerns over right laparoscopic donor nephrectomy unwarranted? Ann Surg. 2001; 233:645.
Husted TL, Hanaway MJ, Thomas MJ, Woodle ES, Buell JF. Laparoscopic right living donor nephrectomy. Transplant Proc. 2005; 37:631.
Mandal AK, Cohen C, Montgomery RA, Kavoussi LR, Ratner LE. Should the indications for laparascopic live donor nephrectomy of the right kidney be the same as for the open procedure? Anomalous left renal vasculature is not a contraindication to laparoscopic left donor nephrectomy. Transplantation. 2001; 71:660.