

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

Submission date 23/08/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/08/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 07/10/2021	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

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

Acronym
LAPNIER

Study objectives

The hypothesis was that donors who underwent a right sided Hand-Assisted Laparoscopic Donor Nephrectomy (HALDN) would have a shorter operation time.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/03/2002, Medical Ethical Commission, ref: MEC 02/225 # 02.17.1158

Primary study design

Interventional

Study design

Randomized active-controlled parallel-group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hand-Assisted Laparoscopic Donor Nephrectomy (HALDN)

Interventions

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 mobilised. 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, mobilisation and postoperative care.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Operation time, measured during operation.

Key secondary outcome(s)

1. Donor morbidity, measurements were prospectively collected
2. Warm ischaemia time, measured during operation

3. Delayed graft function, measurements were prospectively collected
4. Urological complications, measurements were prospectively collected
5. Graft survival, measurements were prospectively collected until one year after transplantation when most patients went to peripheral centers
6. Quality of life, measured using the following questionnaires:
 - 6.1. 36-item Short Form Health Survey (SF-36): donors received these forms preoperatively and at 1, 2, 4, weeks, 3, 6 and 12 months
 - 6.2. Gastro-Intestinal Quality of Life index (GIQLI): donors received these forms preoperatively and at 1, 2, 4, weeks, 3, 6 and 12 months
 - 6.3. Multidimensional Fatigue Inventory-20 (MFI-20) was administered preoperatively and at 1, 3, 6 and 12 months
 - 6.4. Visual analogue scale (VAS) was measured preoperatively and at day 1, 2, 3, 7 and 28

Completion date

14/09/2006

Eligibility

Key inclusion criteria

1. Donors with age above 18 years
2. An identical kidney with regard to renal vascular anatomy
3. Renal function and urinary tract
4. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

60

Key exclusion criteria

1. Unilateral multiple renal arteries

Date of first enrolment

15/04/2002

Date of final enrolment

14/09/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		27/07/2008	07/10/2021	No	No