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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomized active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Operation time, measured during operation.

Secondary outcome measures
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

Overall study start date
15/04/2002

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

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
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1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Surgery
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

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

Study outputs

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