HARP II-trial: Right-sided hand-assisted retroperitoneoscopic live donor nephrectomy versus standard laparoscopic living donor nephrectomy.

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To determine the best approach for right-sided live donor nephrectomy i.e. to optimise donor*s safety and comfort .

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36331

Source
ToetsingOnline

Brief title
HARP II-trial

Condition

- Other condition

Synonym
healthy live kidney donors

Health condition

gezonde nierdonoren

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hand-assisted, live donor nephrectomy, Retroperitoneal, Right-sided

Outcome measures

Primary outcome

Primairy: Operation time, time from the first incision till the closure of the

last incision.

Secondary outcome

Secondary:

Physical functioning, as a measure for the quality of life one month after

operation.

Other secondary endpoints: conversion to open surgery, complications, pain

perception, work resumption, other dimensions of quality of life (SF-36).

Study description

Background summary

Transplantation is the only treatment offering long-term benefit to patients with chronic kidney failure. As the number of patients suffering end stage renal disease (ESRD) increases, the recruitment of more kidney donors is important. Live kidney donation is the most realistic option to reduce donor shortage on short- and long-term. Increasing the number of donors will decrease the number of patients on the waiting list and consequently reduce patient*s mortality. Implementation of live donation offers the possibility to transplant before the kidney disease reaches the terminal phase, necessitating dialysis. Thus, this so called pre-emptive transplantation may prevent unnecessary surgical interventions to establish dialysis (including costs and mortality) and dialysis related complications. In the last decade the number of

non-related live kidney donations is rising. Among these donors are family and friends of the recipient, and even anonymous donors; the ethical basis for live kidney donation is altering. The looser the connection between the donor and recipient is, the less clear the profit for the donor is.
Live donor nephrectomy is performed on healthy individuals who do not receive direct therapeutic benefit of the procedure themselves. In order to guarantee safety for the donors, it is important to optimise the surgical approach.
Recently we demonstrated the benefit of laparoscopic nephrectomy (LDN) to the donor. However, this method is characterised by higher in-hospital costs, longer operating times and requires a well-trained surgeon. The hand-assisted retroperitoneoscopic technique (HARP-technique) may be an alternative to a complete laparoscopic, transperitoneal approach. The peritoneum remains intact and the risk of visceral injuries is reduced. The hand-assistance results in a faster procedure and a significantly reduced operating time. The feasibility of this method has been demonstrated recently, but as to date studies advocating the use of one technique above the other are lacking. This randomised controlled trial compares the right-sided hand-assisted retroperitoneal approach to the current standard, the transperitoneal laparoscopic technique, to define the most optimal approach.
We recently proved that laparoscopic kidney donation is beneficial for the donor. In comparison to minimally invasive open techniques, laparoscopic kidney donation is associated with a better quality of life, less pain, shorter in hospital stay and earlier return to work. This method is expensive for the hospital, has a long operating time and requires an experienced, well-trained, surgeon. Other studies showed a possibly increased rate of life threatening complications, such as injuries to the intestines and bleeding. A surgical approach that is easier to learn and applicable in the majority of donors (i.e. selection of donors is not required) with similar benefits as the transperitoneal laparoscopic approach is warranted.
The right-sided hand-assisted retroperitoneoscopic approach may be a viable alternative. With this method the surgeon inserts his hand to create a retroperitoneal space, which is thereafter insufflated with gas. The peritoneum stays intact and tactile sensation remains. The chance of a complication to the intestines is very small. Furthermore, this technique is easier and quicker to learn for the surgeon than the laparoscopic approach. In the Erasmus MC we perform a randomised trial to compare these techniques for left-side donor nephrectomy (HARP-trial). We also want to know if the operation time is diminished in the right-sided donor nephrectomy, as this is not discribed in literature.

Study objective

To determine the best approach for right-sided live donor nephrectomy i.e. to optimise donor*s safety and comfort .

Study design

The HARP II-trial is a single-centre, randomised controlled, single-blind trial. The study compares hand-assisted retroperitoneoscopic donor nephrectomy and standard laparoscopic donor nephrectomy for the right-sided approach. In total 40 live kidney donors will be included in the study.
Randomisation will take place after endotracheal intubation, by means of telephonic consultation of the study coordinator. A computer generated randomisation list with hidden block size is made for each centre by the statistician. The donor and the physicians involved in the postoperative period are blinded to the surgical technique until one year after donor nephrectomy. The operating theatre is not accessible for people who do not join the operating team. An independent surgeon evaluates the donor on the outpatient clinic before operation. As the extraction incision is similar in both techniques, we did not attempt to cover the wounds with a standard pattern of bandages [12]. All donors fill out the questionnaires until one year after donation, the Short-form 36 (SF-36), Euroqol (EQ-5D), Visual Analogue Scale (VAS) and a questionnaire about work and homecare.

Patient selection
All, properly Dutch speaking, live kidney donors who are medically capable of donating their left kidney can be included in the HARP II-trial. Informed consent is mandatory. All types of live kidney donors can participate in the study, i.e. related, unrelated, altruistic and cross-over live kidney donors. Exclusion criteria are a history of kidney surgery or adrenal gland surgery on the right side.

All potential donors are informed about the study at the outpatient clinic. For further information the patient can refer to the research fellow, transplant surgeon, or the independent physician. If a patient does not sign the informed consent form, the patient is not included in the study and therefore will be operated via the standard protocol. A live kidney donor can always withdraw his or her consent at anytime during the study.

Intervention

Both procedures were performed with the donor placed in right-decubitus position. LDN was performed as described earlier. Shortly, a 10-mm trocar was introduced under direct vision. The abdomen was insufflated carbon dioxide to 12 cm H2O pressure. A 30º video endoscope and 3 to 4 additional trocars were introduced. The colon was mobilized and displaced medially. Opening of the renal capsule and division of the perirenal fat was facilitated using an ultrasonic device (Ultracision, Ethicon, Cincinnati, USA). After identification and careful dissection of the ureter, the renal artery and the renal vein, a pfannenstiel incision was made. An endobag (Endocatch, US surgical, Norwalk, USA) was introduced into the abdomen. The ureter was clipped distally and divided. The renal artery and vein were divided using an endoscopic stapler and the kidney was placed in the endobag and extracted through the pfannenstiel incision.

In HARP we started with a 7-10 cm pfannenstiel incision. After blunt dissection to create a retroperitoneal space, the Gelport (Applied Medical, Rancho Santa Margarita, California, USA) was inserted. Blunt introduction of the first trocar between the iliac crest and the handport was guided by the operator*s hand inside the abdomen. CO2 was insufflated retroperitoneally to 12 cm H2O pressure. Two other 10-12 mm trocars, respectively just outside the midline inferior to the costal margin and in the flank, were inserted to create a triangular shape. For dissection the aforementioned ultrasonic device was used. Dissection of the kidney and renal vessels was similar to transperitoneal donor nephrectomy but with hand-assistance and from a slightly different angle. The kidney was removed manually.

Study burden and risks

3 hours, for filling ou the questionnaires

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

right-sided live kidney donors

Exclusion criteria

previous renal or adrenal surgery, not able to read dutch

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	21-02-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	23-06-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL32401.078.10