Hand-assisted retroperitoneoscopic versus standard laparoscopic donor nephrectomy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21215

Source
Nationaal Trial Register

Brief title
HARP-trial

Health condition

live kidney donors, surgical technique
nierdonatie bij leven, chirurgische techniek

Sponsors and support

Primary sponsor: Erasmus MC, Prof. dr. J.N.M. IJzermans
Source(s) of monetary or material Support: - Mrace efficiency research, Erasmus MC
- Fonds Nuts-Ohra

Intervention

Outcome measures

Primary outcome

Primary study parameters/outcome of the study:

- Physical function, which is a dimension of quality of life. This is measured with the SF-36 questionnaire and includes items like walking stairs and carrying groceries.

Secondary outcome

Secondary study parameters/outcome of the study:

- Costefficacy from a healthcare and societal perspective

- Intra- and postoperative complications

- Other quality of life dimensions

- Postoperative pain-recovery

- Hospital stay and resumption of work

- Kidney function of donor and recipient

- Transplantfunction of the recipient.

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 increases, the recruitment of more kidney donors is important. Live kidney donation is the most realistic option to reduce donor shortage. Increasing the number of donors may reduce patient's mortality and decrease the transplantation waiting list.
Implementation of live donation offers the possibility to transplant before the kidney disease reaches it's terminal phase necessitating dialysis. Thus, this so called pre-emptive transplantation may prevent unnecessary surgical intervention to establish dialysis (including costs and mortality). To date the number of non-related live kidney donations is rising.

Living kidney donor nephrectomy is performed on healthy individuals who receive no direct therapeutic benefit of the procedure themselves. In order to guarantee donor's safety, it is important to optimise the surgical approach. Recently we demonstrated the benefit of laparoscopic nephrectomy to the donor. However, this method is characterized by high costs, long operation times and requires a well-trained surgeon. Especially on the left side we experience more intra-operative complications. An alternative to the fully laparoscopic approach may be the hand-assisted retroperitoneoscopic technique.
The peritoneum remains intact and the risk of visceral injuries is reduced. Due to the hand-assistance the procedure is fast and the time on the operation table may be reduced

significantly. The feasibility of this method has been demonstrated recently , but as to date there are no data available advocating the use of one technique above the other. This randomised controlled trial compares the hand-assisted retroperitoneal approach to the current standard, the transabdominal laparoscopic technique, to define the most optimal approach for left-sided donor nephrectomy.

Study objective

To determine the best approach for left-sided live donor nephrectomy to optimise donor's safety and comfort while reducing donation related costs, with equal or better quality of life for the HARP-technique.

Study design

N/A

Intervention

This trial randomizes donors for either laparoscopic or hand-assisted retroperitoneoscopic (HARP) donor nephrectomy to assess the role of HARP for kidney donation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Potential participants are those willing and approved to donate a kidney by life.

2. Participants must be able to donate the left kidney, not have undergone kidney or adrenal gland surgery on the left side and understand English sufficiently to fill out the questionnaires.

Exclusion criteria

1. Participants must not have undergone kidney or adrenal gland surgery on the left side and understand English sufficiently to fill out the questionnaires.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-07-2008
Enrollment:	190
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-09-2008
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	NL1371
NTR-old	NTR1433
Other	: MEC-2007-198
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A