Right-sided Hand-Assisted RetroPeritoneoscopic versus standard laparoscopic donor nephrectomy.

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To determine the best approach for right-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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25138

Bron
NTR

Verkorte titel
HARP-II

Aandoening

Donor nephrectomy, Live kidney donors

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: MRace Comittee, Fonds Nuts-Ohra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Surgery time.

Toelichting onderzoek

Achtergrond van het onderzoek

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. 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 right-sided donor nephrectomy.

Doel van het onderzoek

To determine the best approach for right-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.

Onderzoeksopzet

Follow-up will be one year.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-10-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2949
NTR-old	NTR3096
Ander register	METC Erasmus MC : 2010-168
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A