

Optimalisation of the perioperative treatment in kidney donors: Fast track perioperative care program vs standard perioperative care program in hand-assisted laparoscopic donornephrectomy.

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Determine whether fast track perioperative care program is preferred above standard perioperative care program in hand-assisted laparoscopic donornephrectomy.

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

Samenvatting

ID

NL-OMON19887

Bron

NTR

Verkorte titel

FAST TRIAL

Aandoening

Kidney transplantation,
laparoscopy,
donor nephrectomy,
fast track perioperative care program

Niertransplantatie,
laparoscopie,
donor nefrectomie
fast track strategie

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Surgery

Overige ondersteuning: Academic Medical Center (AMC), Department of Surgery

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is physical function measured with the SF-36 questionnaire one week after kidney donation.

Toelichting onderzoek

Achtergrond van het onderzoek

Kidney transplantation has become an established therapy for end stage renal disease. With the advent of laparoscopic living donor nephrectomy a reduction in hospital stay, less postoperative analgesic requirements, improved cosmetics, less postoperative pain and an earlier return to normal daily activities have been reported. Both open and laparoscopic donor nephrectomy have same outcome in morbidity and mortality. The introduction of the fast track perioperative care program has proven its value in many surgical operations. The fast track perioperative care program consists of preoperative counselling, no preoperative fasting but carbohydrate-loaded liquids until 2 h before surgery, tailored anaesthesiology encompassing thoracic epidural anaesthesia and short-acting anaesthetics, short incisions, non-opioid pain management, no routine use of drains and nasogastric tubes, early removal of bladder catheters and early and enhanced postoperative feeding and mobilization. Data of fast track surgery of colon malignancies proved that patients had better outcome with regard to ileus, cardiopulmonary function and muscle function compared to standard perioperative care program. The research question is whether fast track perioperative care program is preferred above standard perioperative care program in hand-assisted laparoscopic donornephrectomy.

Doel van het onderzoek

Determine whether fast track perioperative care program is preferred above standard perioperative care program in hand-assisted laparoscopic donornephrectomy.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Fast track program combines various techniques including epidural or regional anaesthesia, minimally invasive techniques, optimal pain control, and aggressive postoperative rehabilitation, including early enteral (oral) nutrition and ambulation. The control group will receive our normal perioperative care including a preoperative enema and postoperative patient-controlled analgesia. The length of the fast track program will be between 48 and 72 hrs.

Specific preoperative donor evaluation included blood and urine examination, angiography, pyelography and renal scintigraphy.

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 mobilized. 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).

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Surgery, P.O. Box 22660
R.C. Minnee
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5664580

Wetenschappelijk

Academic Medical Center (AMC), Department of Surgery, P.O. Box 22660
R.C. Minnee
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5664580

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria:

1. Informed consent;
2. Age above 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria:

1. Expected problems by inserting epidural catheter;
2. No fluency in Dutch language;
3. Use of psychofarma;
4. Chronic use of analgetics;
5. Use of NSAIDs shorter than 5 days before operation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	10-01-2009
Aantal proefpersonen:	64
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	27-10-2009
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	NL1964
NTR-old	NTR2080
Ander register	ABR : 20188
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

- 1 Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients: Transplant Data 1994-2003. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation, Rockville, MD; United Network for Organ Sharing, Richmond, VA; University Renal Research and Education Association, Ann Arbor, MI.

- 2 Terasaki PI, Cecka JM, Gjertson DW, et al. High survival rates of kidney transplants from spousal and living unrelated donors. N Engl J Med. 1995; 333:333-6.

- 3 Merlin TL, Scott DF, Rao MM, et al. The safety and efficacy of laparoscopic live donor nephrectomy: a systematic review. Transplantation. 2000; 70:1659-66.

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- 5 Basse L, Jakobsen DH, Billesbølle P, Werner M, Kehlet H. A Clinical Pathway to Accelerate Recovery After Colonic Resection. Ann Surg 2000; 232: 51-7.

- 6 Basse L, Thorbol JE, Lossel K, Kehlet H. Colonic surgery with accelerated rehabilitation or conventional care. Dis Colon Rectum 2004, 47: 271-278.

- 7 Basse L, Raskov HH, Jakobsen H, Sonne E, Billesbølle P, Hendel HW et al. Accelerated postoperative recovery programme after colonic resection improves physical performance, pulmonary function and body composition. Br J Surg 2002, 89: 446-53.

- 8 Kehlet H, Dahl JB. Anaesthesia, surgery, and challenges in postoperative recovery. Lancet. 2003 Dec 6;362:1921-8.

- 9 Cook T.M. Combined spinal-epidural techniques. Anaesthesia. 2000 Jan;55(1):42-64.

- 10 Abraham NS, Young JM, Solomon MJ. Meta-analysis of short-term outcomes after laparoscopic resection for colorectal cancer. BJS 2004, 91: 1114-1124.

- 11 Marret E, Remy C, Bonnet F; Postoperative Pain Forum Group. Meta-analysis of epidural analgesia versus parenteral opioid analgesia after colorectal surgery. Br J Surg. 2007 Jun;94(6):665-73.