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

No registrations found.

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

Summary

ID

NL-OMON19887

Source
Nationaal Trial Register

Brief title
FAST TRIAL

Health condition

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

Niertransplantatie,
laparoscopie,
donor nefrectomie
fast track strategie

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Surgery
Source(s) of monetary or material Support: Academic Medical Center (AMC), Department of Surgery

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The secondary enpoints are: hospital stay of the donor including readmission in 30 days and cost effectiveness.

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria:

1. Informed consent;

2. Age above 18 years.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2009
Enrollment:	64
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-10-2009
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	NL1964
NTR-old	NTR2080
Other	ABR : 20188
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

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.
4 Tooher RL, Rao MM, Scott DF, et al. A systematic review of laparoscopic live-donor nephrectomy. Transplantation. 2004; 78:404-14.
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, Lossl K, Kehlet H. Colonic sugery with accelerated rehabilitation or conventional care. Dis Colon Rectum 2004, 47: 271-278.
7 Basse L, Raskov HH, Jakobsen H, Sonne E, Billesbolle 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.
10Abraham 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.