Preoperative DNIC testing to identify patients at risk for postoperative pain after living donor nephrectomy.

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Whether the DNIC test can be used to make a prediction of postoperative pain perception and consumption of analgesics after live donor nephrectomy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36057

Source
ToetsingOnline

Brief title
Preoperative DNIC testing in LDN.

Condition

- Other condition
- Nervous system, skull and spine therapeutic procedures

Synonym
nephrectomy, pain

Health condition

geen aandoening, onderzoek bij (in principe) gezonde donoren

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: DNIC, Living donor nephrectomy, Painmanagement

Outcome measures

Primary outcome

Can the DNIC test be used to make a prediction of postoperative pain perception

and consumption of analgesics after live donor nephrectomy?

Secondary outcome

Is there a correlation between the quality of life and pain perception and

consumption of analgesics? Other outcome measures are: hospital stay, return to

normal daily activities, intra and postoperative complications.

Study description

Background summary

Live donor nephrectomy is performed on healthy individuals who do not receive direct therapeutic benefit of the procedure themselves. Due to supreme minimal invasive procedures nowadays, research is not only focussed on the fine-tuning of these techniques, but also on the quality of life and postoperative pain. A shift in emphasis to developing future techniques that enhance quality of life is seen, and there is a growing need for a shift to value-conscious research instead of fostering the *progress at any price* attitude. The donors, the minimal invasive surgical procedures, the perioperative anesthesia and postoperative analgesia techniques are in all procedures very comparable. Despite the uniform approach a large variation is seen in postoperative pain. One of the explanations could be an individually difference in diffuse noxious inhibiting control (DNIC). Pain impulses travelling through the ascending pathways of the somatosensory nervous system can be modulated in several ways. A potentially strong inhibiter of impulse transfer on spinal level is the DNIC. The functionality of DNIC seems to be a predictor for acute post surgical pain

and chronic postsurgical pain. The functionality of this pain-inhibitory system can be easily tested in an experimental setting with quantitative sensory testing techniques. DNIC is maximally activated by for instance an ice water challenge. By applying a sensory stimulus, for example heath or electricity, sensory thresholds of perception, pain and pain tolerance can be estimated before and after activation of the DNIC. Therefore, studies on DNIC can help us to evaluate impairments in descending pain modulation, presumably primarily of inhibitory nature. Preoperative pain registration with questionnaires combined with DNIC testing is a potential predictor for postoperative pain perception. In the unique group of healthy living kidney donors it is important to set a high standard of care and try to minimize all *side-effects* of the operation. If the function of DNIC is disturbed this will presumably lead to more postoperative pain. Insight in the differences in DNIC would give us the opportunity to intervene and develop a *tailor-made* management for each specific patient. In the Erasmus MC we use a standard protocol for analgesic use postoperative. All patients receive a *patient controlled analgesia* device (PCA) and paracetamol per protocol. The amount of analgesic is registered, as well as *escape medication* for donors who have severe postoperative pain.

Study objective

Whether the DNIC test can be used to make a prediction of postoperative pain perception and consumption of analgesics after live donor nephrectomy.

Study design

Single-center, prospective observational study without invasive measurements.

Study burden and risks

The burden and risks associated with participation are limited to the DNIC-testing, and will consume approximately two hours in total. The number of blood samples, the number of site visits and physical examinations is the same as in the current standard protocol for live donor nephrectomy. Participants are asked to give a pain score using the visual analogue scale at one day before surgery, day 0, three times a day up until the day they are discharged and at one month after nephrectomy. Participants are asked to fill out the EuroQol questionnaire preoperatively, at the day they are discharged and at one month after nephrectomy. Participants are asked to fill out the SF-36 questionnaire preoperatively and at one month after nephrectomy. The risks of this study are negligible since the DNIC-test has been validated and is already extensively used in other studies investigating pain perception.

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

Adult living kidney donors. Donors must be older than 18 years and fully comprehend the Dutch language.

Exclusion criteria

Donors younger than 18 years. Donors who not fully comprehend the Dutch language. Mental retardation.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-08-2011
Application type:	First submission
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	NL36751.078.11

Study results

Date completed:	06-02-2012
Actual enrolment:	20