

Pre-operative DNIC testing to identify patients at risk for postoperative pain after living donor nephrectomy

Submission date 26/11/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/02/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/02/2013	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

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. Despite the uniform approach a large variation is seen in postoperative pain. One of the explanations could be an individual difference in diffuse noxious inhibiting control (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. 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 sideeffects 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.

Who can participate?

Any live kidney donor older than 18 years can participate in this study.

What does the study involve?

Pre-operatively, included donors undergo the DNIC-test. The device that will be used is the STMISOL-device from BIOPAC Systems Inc. The donor will be asked what his or her dominant arm is, after which the donor lies down and will be connected through several wires from the contra lateral groin to a computer. Through these wires an increasing stimulus is given. The donor is capable of stopping the stimulus at any time. An extra emergency-button is installed. Three thresholds are measured, namely the threshold when the stimulus is first felt, the threshold when the stimulus becomes painful and the threshold when the pain tolerance is reached. These measurements are repeated three times. Afterwards, the donor is asked to put his or her dominant (contra lateral) hand in ice-water (2°C) for as long as possible (maximum 3 minutes). Then the measurements as mentioned above are repeated, again 3 times. The

difference between the thresholds is an estimate of the DNIC function. Donor nephrectomy will take place following standardized techniques. Postoperative analgesics will be given per protocol, donors receive a patient-controlled analgesia (PCA)-device and oral analgesics (paracetamol). Donors will be asked to keep track of their pain score and fill out questionnaires. There are no further additional procedures.

What are the possible benefits and risks of participating?

There are no direct benefits for the donor. 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.

Where is the study run from?

The study only runs in the Erasmus MC, University Medical Center Rotterdam, the Netherlands.

When is the study starting and how long is it expected to run for?

The study started in October 2011 and was completed in February 2012.

Who is funding the study?

Erasmus MC, University Medical Center.

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NL36751.078.11

Study information

Scientific Title

Pre-operative DNIC testing to identify patients at risk for postoperative pain after living donor nephrectomy

Study objectives

Can the diffuse noxious inhibitory controls (DNIC) test be used to make a prediction of postoperative pain perception and consumption of analgesics after live donor nephrectomy?

Secondary objectives:

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Research Committee (METC) of the Erasmus Medical Centre in Rotterdam, The Netherlands, 23 August 2011, Ref.nr.: MEC-2011-212 NL36751.078.11

Study design

Single-center observational prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Postoperative pain perception after live donor nephrectomy

Interventions

As standard, the kidney donors will be admitted one day prior to surgery. On this day they will undergo the DNIC-test. The DNIC-test will be performed by only one person, qualified to do this test. The device that will be used is the STMISOL-device from BIOPAC Systems Inc.* This device is one of the most accurate to measure pain perception and pain tolerance. The donor will be asked what his or her dominant arm is, after which the donor lies down and will be connected through several wires from the contralateral groin to a computer. Through these wires an

increasing stimulus is given. The donor is capable of stopping the stimulus at any time. An extra emergency-button is installed. Three thresholds are measured, namely the threshold when the stimulus is first felt, the threshold when the stimulus becomes painful and the threshold when the pain tolerance is reached. These measurements are repeated three times. Afterwards, the donor is asked to put his or her dominant (contralateral) hand in ice-water (2°C) for as long as possible (maximum 3 minutes). Then the measurements as mentioned above are repeated, again three times. The difference between the thresholds is an estimate of the DNIC function. Donor nephrectomy will take place following standardized techniques. Postoperative analgesics will be given per protocol, donors receive a patient-controlled analgesia (PCA)-device and oral analgesics (paracetamol). Donors will be asked to keep track of their pain score [Visual Analogue Scale (VAS-score)] fill out a quality of life questionnaire (SF-36) and fill out the EuroQol (EQ-5D) questionnaire at different times. There are no further additional procedures.

*. The quality management system of BIOPAC Systems, Inc. has been assessed by NSFISR and found to be in conformance to the following standard(s): ISO 9001:2008.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

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

Secondary outcome measures

1. Is there a correlation between the quality of life and pain perception and consumption of analgesics?
2. Hospital stay
3. Return to normal daily activities
4. Intra and postoperative complications

Overall study start date

03/10/2011

Completion date

06/02/2012

Eligibility

Key inclusion criteria

1. Adult (>18 years) living kidney donors
2. Donors must fully comprehend the Dutch language

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

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

Date of first enrolment

03/10/2011

Date of final enrolment

06/02/2012

Locations**Countries of recruitment**

Netherlands

Study participating centre**Department of Anesthesiology**

Rotterdam

Netherlands

3015 CE

Sponsor information**Organisation**

Erasmus Medical Centre (Netherlands)

Sponsor details

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Rotterdam

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j.lafranca@erasmusmc.nl

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus MC, University Medical Center (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration