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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

Registration date
25/02/2013

Overall study status
Completed

Last Edited
25/02/2013

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
J.A. Lafranca, MD, PhD-candidate
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus MC, University Medical Center (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	Participant information sheet				

Participant information sheet	11/11/2025	11/11/2025	No	Yes