Long-term follow-up after live kidney donation; A matched, controlled study on renal function and quality of life.

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To assess the long-term consequences of live kidney donation, regarding kidney function, survival, hypertension, diabetes, systolic and diastolic blood pressure, mental state and quality of life.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON40045

Source
ToetsingOnline

Brief title
LOVE-study

Condition

- Anxiety disorders and symptoms
- Renal disorders (excl nephropathies)
- Vascular hypertensive disorders

Synonym
Kidney function

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: Follow-up, Kidney function, Live kidney donation, Survival

Outcome measures

Primary outcome

Kidney function, measured by serum creatinin and estimated GFR (calculated by

the MDRD and CKD-EPI-formula).

Secondary outcome

o Donor survival

o Incidence of hypertension

o Incidence of diabetes mellitus

o Systolic and diastolic bloodpressure

o Size of the contralateral kidney on ultrasonography

o Quality of life, measured by the SF-12 and EuroQoL questionnaires

o Incidence of fatal and non-fatal cardiovasculair events

o Protein/creatinine ratio and microalbuminuria

o Creatinine in urine

o Glucose in blood and urine

o Mental state: depression, anxiety, happiness, sexuality, sleep disorders

Study description

Background summary

Living donors are healthy people necessitating a high standard of care to guarantee their quality of life after donation. Moreover, optimizing the

quality of life after an operation performed for the well-being of another individual is the legitimization for any living organ donor program. In the last decade multiple innovations in live donor nephrectomy have been introduced, thereby expanding the donor pool. However, little is known on the long-term effects of live kidney donation, regarding kidney function, diabetes, hypertension, survival and quality of life. Determining the effects of live kidney donation on long term is pivotal to continue the expanding inclusion of living donors in the kidney donation programme. Screening for potential donors will be more complete and effective when a more accurate risk assessment can be provided. Also, accurate information to donors and corresponding recipients on these risks is a prerequisite to include donors with minor risk factors, like hypertension, obesity and more in the national live kidney donation programme. With the availability of the live kidney donor cohort, the Rotterdam Study-cohort in Rotterdam and the SHIP-study cohort we have the unique opportunity to determine the long term effects of kidney donation. For the first time it will be possible to study the long term consequences live kidney donation in a matched and prospective study design. This study will offer a reference indicating safety criteria related to living kidney donation in the Western world.

Study objective

To assess the long-term consequences of live kidney donation, regarding kidney function, survival, hypertension, diabetes, systolic and diastolic blood pressure, mental state and quality of life.

Study design

Long-term follow-up in donors and donors with comorbidities: a prospective, matched cohort study.

Patients: All donors in our database are eligible for inclusion in this study. All donors were pre-operatively screened by a nephrologist and surgeon. A medical psychologist is consulted on indication and in case of unspecified donation. Radiological evaluation of their kidneys took place by ultrasonography, magnetic resonance imaging and computed tomography angiography. Donor nephrectomy was performed by using a variation of open and endoscopic techniques. The RS-II and RS-III cohort will be used as a control group in this study for donors aged 45 and higher. In total 3011 controls have been included in the RS-II cohort in 2000-2001, they were followed up on in 2004-2005. The RS-III cohort started including for this cohort in 2006, this time with inhabitants aged 45 years and over. Inclusion ended in December 2008 and 3,932 participants have been included in this third cohort. The first follow-up moment of this cohort will start in 2012 and is due to finish in 2013. The first cohort of the SHIP-study will be used as a control group in this study for donors aged 44 and younger. This cohort includes 4,310

participants aged 20-70 years.

Methods: Donor characteristics and follow-up data will be checked and updated in accordance with the hospital*s electronic patient system. As soon as approval of the Medical Ethical Committee has been acquired, donors will be contacted and asked to participate in this study. If they choose to participate, a follow-up visit at our outpatient clinic will be scheduled. During this visit blood and urine samples will be taken and an ultrasonography of the remaining kidney will be performed. Donors will undergo blood pressure tests and receive a questionnaire on their drug usage, the development of cardiovascular disease, quality of life and mental state. All answers on these questionnaires will be discussed with a physician. Furthermore, their complete medical history will be checked. Non-responders will be contacted and asked if they object if information from their medical records will be used for this study (e.g. kidney function from blood and urine analysis, blood pressure, weight, medication use, incidence of comorbidity) and if they want to fill out a quality of life questionnaire. Controls will be selected and matched for age, gender, BMI, ethnicity and pre-existing co-morbidity. After matching, all study parameters will be compared to our control group. A 1 on 4 match is our goal, however if the available data in the control group is insufficient, this will have to be revised downwards. Donor survival will be crosschecked in the municipal registry and compared to the general Dutch population. All data regarding the controls will be acquired from the Rotterdam Study and SHIP study database.

Measurements: Systolic and diastolic tension will be measured using a datascope. Blood samples will be taken and serum creatinine, glucose and eGFR according to MDRD and CKD-EPI-formula will be measured. Protein/creatinin ratio, glucose, creatinine and microalbuminuria will be measured in the donor*s urine. Development of related co-morbidity, drug usage etc. will be assessed by a questionnaire, with the help of a physician. Quality of life will be measured with the SF-12 and EuroQoL questionnaire. Mental state will be measured with the HADS, PSIQ, CESD (or BDI if donor is aged 44 or younger), questionnaire on sexuality and happiness.

Statistical considerations: The Kaplan-Meier method will be used to calculate donor and control survival, differences will be tested using the log-rank test. Multivariate Cox regression analysis will be performed to assess independent prognostic factors regarding kidney function and comorbidities. Differences between groups will be analyzed using the paired-samples T-test and the one-way ANOVA.

Ten-year follow-up on quality of life.
All 143 donors that were included in the Lido-trial between 2001 and 2003 are eligible for inclusion in this study; deceased or emigrated donors will be excluded. All donors were pre-operatively screened by a nephrologist. A medical psychologist is consulted on indication and in case of unspecified donation.

Radiological evaluation of their kidneys took place by ultrasonography, magnetic resonance imaging and computed tomography angiography. Donor nephrectomy was performed by either mini-incision or laparoscopically.
Methods: Donors filled out two questionnaires regarding quality of life pre-operatively and at 1, 3, 6 and 12 months post-operatively. Ten years after donation donors will be contacted by mail. They will be requested to fill out the same two questionnaires; non-responders will be contacted again by mail and telephone. A response rate of 70% will be deemed acceptable.
Statistical considerations: Quality of life scores will be adjusted for baseline values and gender. A logistic regression analysis will be carried out. Categorical variables will be compared using the Chi square test, continuous variables will be tested using the Mann Whitney U test and repeated measurements will be tested by repeated measurements ANOVA, using SPSS mixed models.

Study burden and risks

Not applicable

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

All donors that underwent a live donor nephrectomy between 1981 en 2010 are eligible for inclusion. Donors that have deceased will not be approached.

Exclusion criteria

Donors must be capable of filling out the questionnaires in Dutch.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2013
Enrollment:	1080
Type:	Actual

Ethics review

Approved WMO Date:	18-12-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-07-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-11-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-12-2014
Application type:	Amendment
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

ID: 24471
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42270.078.12
Other	TC 3795
OMON	NL-OMON24471