Informed Consent Procedures in Live Donor Nephrectomy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20363

Source
NTR

Brief title
PRINCE

Health condition

Live donor nephrectomy candidates

Sponsors and support

Primary sponsor: Erasmus MC, University Medical Center, Rotterdam
Source(s) of monetary or material Support: Quality Foundation Funds Medical Specialist (Stichting Kwaliteitsgelden Medisch Specialisten, SKMS)
Dutch Kidney Foundation (Nierstichting Nederland)

Intervention

Outcome measures

Primary outcome

- Donor comprehension of the donation procedure

- Elements to be included in standardized informed consent procedure

Secondary outcome

- The manner of obtaining consent in the eight Dutch transplant centers

- Donor satisfaction with the informed consent procedure

- Correlation of donor comprehension with surgeons'estimate thereof

Study description

Background summary

The PRINCE trial aims to evaluate the current status of the informed consent procedure for the live donor Nephrectomy in the Netherlands. Donor comprehension will be assessed by means of pop quizzes and an evaluation and satisfaction questionnaire will be provided to them.
Data collected in this project will be used to create a standardized format for the informed consent procedure for the live donor nephrectomy.

Study objective

Informed consent procedures and information provision differs between different transplantation centers and transplantation professionals in The Netherlands.
Donor knowledge and satisfaction may be influenced by the manner of information provision and the contents of the informed consent procedure.

Study design

There are no explicit timepoints. Inclusion is expected to be finalized by march 30th 2016.

Intervention

- Pop-quiz style knowledge tests

- Satisfaction & evaluation questionnaire

Contacts

Public

Postbus 2040
F.J.M.F. Dor
Erasmus MC, Rotterdam
Afdeling Heelkunde, H-811
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7040704
Scientific
Postbus 2040
F.J.M.F. Dor
Erasmus MC, Rotterdam
Afdeling Heelkunde, H-811
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7040704

Eligibility criteria

Inclusion criteria

- Potential living kidney donor

- Age ≥ 18 years

- Fluent comprehension of Dutch language

Exclusion criteria

- Mental illness prohibiting consent
- No fluent comprehension of Dutch language

- Minor (<18 years of age)

Study design

Design

Study type:	Observational non invasive

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-03-2015
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-08-2015
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	NL5225
NTR-old	NTR5374
Other	: MEC-2014-538

Study results