

# Informed Consent Procedures in Live Donor Nephrectomy

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON20363

### Source

Nationaal Trial Register

### 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**

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## **Eligibility criteria**

### **Inclusion criteria**

- Potential living kidney donor
- Age  $\geq$  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:	N/A: single arm study
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