# The relevance of donorspecific memory B cells in immunised kidney transplant recipients

No registrations found.

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

## Summary

### ID

NL-OMON25271

**Source**
Nationaal Trial Register

**Brief title**
Donorspecific memory B cells in kidney transplantation

**Health condition**

kidney transplant recipients

niertransplantatie patiënten

### Sponsors and support

**Primary sponsor:** Leiden University Medical Center
**Source(s) of monetary or material Support:** Nierstichting Nederland

### Intervention

### Outcome measures

**Primary outcome**

The main parameter to be assessed in the current study is the frequency of donor-specific

memory B cells as determined by a novel ELISPOT based technique. Furthermore, donor-specific antibody levels will be determined by CDC and Luminex techniques.

### Secondary outcome

The secondary study parameters are clinical parameters. The transplant function at 6 and 12 months will be determined by the estimated Glomerular Filtration Rate (eGFR), calculated by the Modification of Diet in Renal Disease (MDRD) formula. Furthermore, the occurrence of cellular and antibody mediated rejection within the first year after transplantation will be recorded.

## Study description

### Study objective

The presence of a broadly reactive anti-donor specific memory B cell compartment is a risk factor for an accelerated memory response after transplantation.

### Study design

Peripheral blood (30 ml per time point) will be drawn by venapuncture at 3 time points (pre-transplant, at 3 and 6 months post-transplantation). Clinical follow-up will be performed up to 1 year after transplantation. In case of a living donor transplant, 30 ml of peripheral blood will be drawn from the kidney donor once before the explantation.

### Intervention

N/A

## Contacts

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# Eligibility criteria

## Inclusion criteria

Patients who will undergo a kidney retransplant and, if applicable, their living kidney donor

## Exclusion criteria

Hepatitis C or HIV seropositive individuals

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-08-2013 |
| Enrollment: | 100 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 16-07-2014 |

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 | NL4553 |
| NTR-old | NTR4695 |
| Other | NL42616.058.12 : P13.025 |

# Study results