# Assessment of sympathetic reinnervation of the kidney allograft with 123I-MIBG scintigraphy

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26074

**Source**
Nationaal Trial Register

**Brief title**
RENnervate study

**Health condition**

kidney transplant recipients with kidney allografts of three various allograft vintage ranges (within 6-18 months after transplantation, 4.5 to 7 years after transplantation and >10years after transplantation).

### Sponsors and support

**Primary sponsor:** Academic Medical Center Amsterdam (AMC)
**Source(s) of monetary or material Support:** AMC

### Intervention

### Outcome measures

**Primary outcome**

To compare allograft sympathetic reinnervation by 123I-MIBG washout rates between

patients with a recent transplantation (6-18 months), patients with an allograft in situ for > 4½ and <7 years and patients who have a kidney transplantant >10 years.

### Secondary outcome

N/A

## Study description

### Background summary

A number of renal transplant recipients have excellent functioning grafts for many years after transplantation. Most obvious this is due to immunological factors, infection rates and comorbidity. However, it is unclear whether renal nerve regrowth in the allograft might influence graft survival. Due to the explantation process, the renal allograft is entirely denervated at time of transplantation. In years after transplantation, it is unknown to what extend and when regeneration of renal sympathetic nerves after transplantation occurs. Assessment of the sympathetic nerve activity (SNA) can be determined by peroneus microneurography or catecholamine levels in plasma. However, these methods are indirect, invasive and impractical and do not supply information about regional sympathetic nerve activity. 123I-metaiodobenzylguanidine (123I-MIBG) is a radio-labeled analogue of noradrenaline and is taken up by presynaptic nor-adrenaline transporters and thereby it can provide an estimate of sympathetic activity. 123I-MIBG scintigraphy has shown to offer prognostic information in patients with heart failure. Since kidney transplantation is the only durable therapy for end stage renal disease, allograft nephropathy remains an important clinical problem. Various lines of evidence suggest that sympathetic denervation of the allograft plays a role in the pathogenesis of allograft nephropathy. Due to the explantation process, the renal allograft is entirely denervated at time of transplantation. There is histological evidence that after transplantation there is re-innervation of the allograft. However, up to 2,5 years after transplantation such reinnervation has been shown not to be of functional significance. Reinnervation is a potential therapeutic aim to prevent allograft nephropathy. We hypothesize that allograft sympathetic reinnervation is a slow process which takes >10 years to reach functional capacity. If there is a >7.5% difference in washout-rate n the kidney graft compared to the mediastinum, we assume that this implicates reinnervation of the graft. We assume that if renal re-innervation occurs, 123I-MIBG uptake will be higher in patients with an older renal allograft compared to recent transplanted allografts that show decreased or lack of 123I-MIBG uptake.Therefore, patients with a graft in situ for > 10 years will be studied initially.

### Study objective

We hypothesize that allograft sympathetic reinnervation is a slow process which takes >10 years to reach functional capacity and thatt 123I-MIBG scintigraphy can assess functional reinnervation of the kidney allograft.

### Study design

Primary data are based on one 123I-MIBG scintigraphy.

### Intervention

All patients will undergo 123I-MIBG scintigraphy. They will receive 185 MBq of 123I-MIBG intravenously. Subsequently at 15 min and 4 hrs and 24 hours post injection planar images are made in combination with SPECT at 4 and 24 hours post injection. The SPECT acquisition is combined with a low dose CT-scan of the abdomen (without intravenous contrast) to relate the 123I-MIBG uptake to anatomical structures.

## Contacts

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## Eligibility criteria

### Inclusion criteria

Recently transplanted patients (n=6)

- Renal graft in situ for 6-18 months at time of measurement or Approximately 5 year renal transplant survivors (n=6);

-Renal graft in situ for > 4¨ö < 7 years at time of measurement

Long term graft survivors (n=6):

- Renal graft in situ for >10 years at time of measurement

All patients have:

- A measured creatinine clearance á 50 ml/min;

- At least one native kidney in situ.

### Exclusion criteria

- Pregnancy;

- Unable to give informed consent;

- Absolute indication for alpha and/or beta-blocking agents.

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 15-05-2013 |
| Enrollment: | 18 |
| Type: | Anticipated |

# Ethics review

Positive opinion
Date: 21-05-2013
Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 39698
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL3837 |
| NTR-old | NTR4005 |
| CCMO | NL42557.018.13 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON39698 |

# Study results

**Summary results**
N/A