

# The effects of antithymocyte globulin (ATG) on the endothelial glycocalyx in kidney transplant recipients

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To determine whether the endothelial glycocalyx is damaged by ATG therapy.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Renal disorders (excl nephropathies)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON34735

### Source

ToetsingOnline

### Brief title

ATG/endothelial glycocalyx/kidney transplantation

### Condition

- Renal disorders (excl nephropathies)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

### Synonym

endothelial glycocalyx and atherosclerosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** ATG, endothelial glycocalyx, kidney transplantation

## Outcome measures

### Primary outcome

The thickness of the endothelial glycocalyx in kidney transplant recipients before and after ATG therapy.

### Secondary outcome

The following parameters will be measured:

- Glycocalyx constituents and glycocalyx regulating enzymes: hyaluronan, heparan sulfate, syndican-1, hyaluronidase en heparanase
- IL-6, CRP

## Study description

### Background summary

Cardiovascular disease is one of the major causes of morbidity and mortality after kidney transplantation. Many of the current immunosuppressive drugs are associated with an increase of systemic risk factors for the development of atherosclerosis like hyperglycaemia and hypercholesterolemia. In the general population, attention has shifted from treating systemic risk factors, towards increasing the vasculo-protective properties of the vessel wall itself. In recent years, it has been recognized that the endothelial glycocalyx may contribute to the vasculo-protective properties of the vessel wall.

In experimental and human studies it has been demonstrated that inflammatory stimuli increase the vulnerability of the vessel wall. Nieuwdorp et al. showed recently that endotoxin challenge and subsequent cytokine release results in a large reduction of both systemic and microvascular glycocalyx volume. Moreover, they observed shedding of the major glycocalyx component hyaluronan, activation of monocytes and the coagulation cascade. The influence of ATG treatment on the endothelial glycocalyx has not been established yet. The hypothesis of the

present study is that ATG infusion will damage the endothelial glycocalyx through the release of cytokines, contributing to an increase in vascular vulnerability in kidney transplant recipients.

### **Study objective**

To determine whether the endothelial glycocalyx is damaged by ATG therapy.

### **Study design**

A case study with interventions. Measurements of the glycocalyx will be performed in kidney transplant recipients receiving ATG treatment because of an allograft rejection. Patients will be admitted to the kidney transplantation ward in the AMC as part of the standard protocol of ATG treatment. The study will take place during the first 24 hours of ATG treatment.

### **Study burden and risks**

The study consists of the following measurements:

- physical examination incl. blood pressure and body weight (part of standard ATG treatment)
- measurement of the glycocalyx (3x)
- blood sampling (7 times in total; 5 times extra compared to standard ATG treatment; total volume 56 ml)

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Female or male, age between 18 and 70 years

Kidney transplant recipient

ATG therapy because of an allograft rejection

Given written informed consent

### Exclusion criteria

Smoking

Diabetes Mellitus

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated):	01-02-2010
Enrollment:	6
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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
CCMO	NL30836.018.10