# Platelet Function During Orthotopic Liver Transplantation. An observational study.

Published: 29-01-2008
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To establish platelet function during orthotopic liver transplantation.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Hepatic and hepatobiliary disorders |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON32329

**Source**
ToetsingOnline

**Brief title**
PLATO-II

### Condition

- Hepatic and hepatobiliary disorders

**Synonym**
end-stage liver disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Bayer,Bayer BV; Tekke Huizinga Fonds.

### Intervention

**Keyword:** coagulation, orthotopic liver transplantation, platelet function, platelets

## Outcome measures

### Primary outcome

Development of functional properties of vWF during and after OLT.

Development of functional properties of platelets during and after OLT.

Circulation of partly activated platelets during OLT (especially after

reperfusion).

### Secondary outcome

Transfusion requirements, which contains all crystalloids, colloids and blood

products as RBCs, FFPs and Trombocytes, during the operation.

Hepatic artery thrombosis.

total blood loss.

# Study description

### Background summary

Despite considerable progress in surgical techniques, orthopic liver transplantation (OLT) is still associated with significant blood loss, resulting in requirement for transfusion of blood products in an substantial number of patients. Before surgery, patients have poorly characterized, multifactorial coagulopathic state, which aggravates perioperatively. One of the contributors to preoperative coagulopathy in patients eligible for OLT is a qualitative and quantitative blood platelet defect. Little is known, however, on the perioperative development of platelet function abnormalities.

### Study objective

To establish platelet function during orthotopic liver transplantation.

### Study design

observational clinical mono-center study.

**Study burden and risks**

Serial samples, containing blood samples and liver biopsies, will be studies during and after liver transplantation.

Blood samples: 4 times during surgery and 3 times (day 1,5 and 10) after surgery.
Liverbiopsies: following standard protocols. two times during surgery and one week after surgery.

The duration of the study per patient will not be longer than the admission time of the patient in the hospital. Patients who participate in the study do not have to come over for extra visits to the hospital.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

age > 17 years
first liver transplantation for liver cirrhosis
retransplantation for liver cirrhosis, more than six months after previous OLT.

### Exclusion criteria

age < 18 years
retransplantation within six months after first/last transplantation.
presence of metabolic disease
malignancies
Budd-chiari syndrome
portal vein thrombosis
use of aspirin 10 days before surgery.

## Study design

### Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2008 |
| Enrollment: | 20 |
| Type: | Anticipated |

## Ethics review

Approved WMO

| | |
|---|---|
| Application type: | First submission |

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

# 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 | NL21105.042.07 |