# Neutrophil viability in surgical patients and its relationship with neutrophil functionality

Published: 04-10-2017
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This study aims to further investigate neutrophil viability as marker for neutrophil cell dead in patients with a decreased leukocyte viability factor and investigate its impact on neutrophil functioning.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Immune disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON49355

**Source**
ToetsingOnline

**Brief title**
Neutrophil viability study

### Condition

- Immune disorders NEC

**Synonym**
death of white blood cells, neutrophil cell death

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** leukocyte, neutrophil, neutrophil viability, surgery

## Outcome measures

### Primary outcome

The primary endpoint is neutrophil cell death, determined by double staining of

Annexin V and PI. This will be compared to the decreased viability factor of

the initial routine blood sample to validate the viability factor.

### Secondary outcome

Secondary endpoints are neutrophil phagocytosis and responsiveness to fMLP.

# Study description

### Background summary

Previous studies showed a decreased neutrophil viability in critically ill patients. Neutrophil viability was measured using propidium iodide (PI) staining, which visualizes diminished membrane integrity and thus cell necrosis or apoptosis. Not much is known about a decreased neutrophil viability and its implications for neutrophil functioning.

### Study objective

This study aims to further investigate neutrophil viability as marker for neutrophil cell dead in patients with a decreased leukocyte viability factor and investigate its impact on neutrophil functioning.

### Study design

prospective cohort series, diagnostic

### Study burden and risks

A total of two 4 milliliter blood containers will be collected from the patients. Sampling this amount of blood will have a negligible influence on total blood volume. In total, one venipuncture is required to obtain the blood

samples and if the patient has a central venous or peripheral arterial catheter in situ, no punctures are required.

## 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

leukocyte viability factor * 0.95

### Exclusion criteria

Immunosuppressive drugs (e.g. chemotoxic and cytostatic drugs) or positive HIV-status or use of clozapine medication

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 31-10-2017 |
| Enrollment: | 33 |
| Type: | Actual |

# Ethics review

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|---|---|
| Approved WMO Date: | 04-10-2017 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 08-03-2018 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 04-04-2018 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 13-02-2019 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL60543.041.17 |