

# Blood donation by healthy volunteers for experimental in-vitro research

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON38115

### Source

ToetsingOnline

### Brief title

Blood donation volunteers

### Condition

- Other condition
- Bacterial infectious disorders

### Synonym

cytokine responses

### Health condition

Breed infectieus en immunologisch klinisch relevante onderwerpen

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Vici

## Intervention

**Keyword:** Blood, Donation, Experiment, In-vitro

## Outcome measures

### Primary outcome

Cytokine responses

### Secondary outcome

N/A

## Study description

### Background summary

Infections are still a leading course of mortality worldwide. Sepsis is associated with a crude mortality of 30-40% and it is currently believed that only adjuvant immunomodulatory therapy will reduce this high mortality. The aim of this research is to contribute to the understanding of the pathophysiology of severe infections, and subsequently provide relevant new insights in the development of new treatment modalities. In-vitro research has proven to be a useful tool to test hypothesis and provide proof of principle in fundamental research. In the present research proposal we would like to ask healthy volunteer to donate blood, which will be used as an ex-vivo model to test various immunotherapeutic strategies.

### Study objective

The aim of this research is to contribute to the understanding of the pathophysiology of severe infections, and subsequently provide relevant new insights in the development of new treatment modalities. In the present research proposal we would like to ask healthy volunteer to donate blood, which will be used as an ex-vivo model to test various immunotherapeutic strategies.

### Study design

Since the design of our regular in vitro studies normally require an amount of 40 ml of EDTA blood or whole blood, it is not an option to use buffy coats which could be an alternative. We therefore request to ask healthy volunteers for blood donation to our lab so in-vitro experiments can be performed. The standard in-vitro work is isolation of peripheral blood cells and or neutrophils. After isolation these cells will be stimulated with various compounds such as microorganisms or recombinant proteins. We then check for expression of cytokines in the supernatants by ELISA and in the cells by PCR or western blotting. These procedures are standard and are performed in the well equipped, experienced and authorized laboratory of the department of Experimental Medicine.

### **Study burden and risks**

Volunteers will be asked to give blood. Discomfort can be experienced when the needle is placed in the vein and the risk of a local hematoma is present. A vasovagal reaction can be experienced. There will be no direct benefit for the participant.

## **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

Healthy volunteers 18-65 year

### Exclusion criteria

- Medication (with the exception of birth control and incidental medication)
- Immunosuppressive status
- Drug user
- Active infection

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 30-01-2012

Enrollment: 1000

Type: Actual

## Ethics review

Approved WMO

Date:	27-01-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	14-04-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	25-06-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	03-01-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	31-08-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL32357.091.10