# Military Aggression Regulation Study

Published: 14-03-2013 Last updated: 24-04-2024

The study\*s objective is to measure neurobiological differences between veterans and military men with aggression regulation problems after deployment and healthy control

participants.

**Ethical review** 

Approved WMO

**Status** 

Recruitment stopped

**Health condition type** Other condition

Study type

Observational invasive

## **Summary**

#### ID

NL-OMON39980

Source

ToetsingOnline

**Brief title** 

**MARS** 

### **Condition**

- Other condition
- Impulse control disorders NEC

### **Synonym**

aggression, anger

**Health condition** 

agressieregulatie problematiek

### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van Defensie

## Intervention

**Keyword:** aggression, impulsivity, MRI, veterans

#### **Outcome measures**

## **Primary outcome**

Differences in amygdala and prefrontal cortex activity, differences in startle response, differences in blood parameters as neuropeptide Y, vasopressin and testosterone, differences in performance on neuropsychological tasks between veterans with aggression regulation problems and healthy control participants.

#### **Secondary outcome**

n.a.

# **Study description**

### **Background summary**

Aggression regulation problems are a common complaint after deployment, however the underlying neurobiology of aggression regulation problems remains unknown. This study aims to examine which neurobiological abnormalities are associated with aggression regulation problems.

## Study objective

The study\*s objective is to measure neurobiological differences between veterans and military men with aggression regulation problems after deployment and healthy control participants.

## Study design

This study is a cross-sectional study with inclusion of a control group.

## Study burden and risks

The burden and risks of this study are: (1) 36 ml of blood will be drawn from the participants, (2) An MRI scan can be perceived as uncomfortable, (3) the

psychological questionnaires and interviews can evoke unwanted feelings. Considering the objective and relevance of this study, this burden is evaluated as negligible.

## **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

For participants with impulsive aggression, the following inclusion criteria:

- Soldiers and veterans (men) who participated in a military deployment (minimum 4 months)
- Age between 18 and 50 years
- Presence of problems with aggression as evidenced by either (I): the A1 or A2 criterion of the research diagnostic criteria for impulsive aggression "(Coccaro, 2012), or (II) evidence for problems with pent-up anger as revealed by answers to the screening questionnaire.
- Written informed consent; For control participants, the following inclusion criteria:

- Healthy men
- Age between 18 and 50 years
- Written informed consent
- No (current) DSM-IV Axis-I disorder
- No evidence of problems with aggression

#### **Exclusion criteria**

- Alcohol / substance abuse and / or dependence
- Severe neurological diseases (eg Parkinson's disease, stroke, MS);Exclusion for MRI procedure:
- Claustrophobia, pacemaker (or other implants), or metal objects in the body causing an MRI scan is not possible.
- Current use of psychotropic drugs (benzodiazepines, antidepressants, antipsychotics, anticonvulsants)

# Study design

## **Design**

Study type: Observational invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 14-05-2013

Enrollment: 100

Type: Actual

## **Ethics review**

Approved WMO

Date: 14-03-2013

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 05-05-2014
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 NL42537.041.12