# Neurobiological Development of Aggressive Behavior: Part I of the Forensic Research & Technology Study (The FoReTech Study)

Published: 23-10-2018
Last updated: 12-04-2024

The main aim of the current study is to identify a set of neurobiological markers that contribute to the prediction, distinction and prevention of reactive and proactive aggressive behavior. The study has two primary objectives: 1) to study whether...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Psychiatric and behavioural symptoms NEC |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON50459

**Source**
ToetsingOnline

**Brief title**
The Foretech Study I

### Condition

- Psychiatric and behavioural symptoms NEC

**Synonym**
Aggressive behavior

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Stichting Vrienden van Oldenkotte

## Intervention

**Keyword:** Aggression, Epidemiology, Forensic Psychiatry, Neurobiology

## Outcome measures

### Primary outcome

1) The association between sensory processing and aggressive behavior will be studied. Sensory processing will be measured using a questionnaire.

2) The association between hormonal values (testosterone and cortisol) and aggressive behavior will be studied. Hormonal values will be obtained from hair samples.

Aggressive behavior, the main outcome, will be measured by two self-report questionnaires, resulting in three outcomes: reactive aggressive behavior, proactive aggressive behavior and total aggressive behavior.

### Secondary outcome

-

# Study description

### Background summary

Aggressive behavior has many adverse effects on victims, perpetrators, their families and society. Nowadays prediction of risk for recidivism is fully based on psychological and social factors and treatment is centered around psychotherapeutic interventions. However, fundamental research has shown that the value of many neurobiological factors in terms of prediction and prevention of aggressive behavior still remains to be unraveled. Innovative technologies potentiate research into biological pathways to aggressive behavior. Specific neurobiological markers of aggressive behavior may provide new insights for prediction and prevention of such behaviors.

### Study objective

The main aim of the current study is to identify a set of neurobiological markers that contribute to the prediction, distinction and prevention of reactive and proactive aggressive behavior. The study has two primary objectives: 1) to study whether sensory processing is associated with aggressive behavior and 2) to study whether the neuroendocrinological hormones cortisol and testosterone are associated with aggressive behavior.

### Study design

The current study is a longitudinal study in which forensic psychiatric patients will be compared to a healthy controls of similar age, sex, educational level and ethnicity. The comparative design makes it possible to study differences between forensic psychiatric patients and healthy controls. For the patients, there will be a follow-up measurement one year after the baseline measurement. This longitudinal design provides the possibility to study change within persons over time related to treatment progression.

### Study burden and risks

All participants will be invited for a baseline visit and an online survey. Only participants of the patient group will be invited for a follow-up visit after one year. The baseline part consists of several measurements in the form of questionnaires, a neuropsychological test and biological measurements such as length, weight, collection of scalp hair and saliva samples. The risks associated with all of these measurements are considered to be negligible. The follow-up visit for patient participants will comprise short repeated measurements of the main outcome variables. Participants receive a monetary compensation for their participation. The current study has the potential to identify several neurobiological markers that may improve the prediction and prevention of reactive and proactive aggressive behavior and the treatment progression of forensic psychiatric patients.

## Contacts

**Public**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
**Scientific**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

In order to be eligible to participate in this study, all patients and controls must meet the following criteria:
- Participant is at least 18 years old.
- Participant has provided written informed consent.
Only patient participants should also meet the following:
- Patient is receiving outpatient care at De Tender.

## Exclusion criteria

Potential patients or control participants who meet any of the following criteria will be excluded from participation in this study:
- There are indications for intellectual disability (IQ < 70).
- The participant does not speak or read Dutch on a proficient level.
- The participant is incapable of deciding on study participation and therefore cannot give informed consent.

Only those patients who can explicitly state that he or she knows that he can refuse participation, that he/she knows what participation in the study encompasses and that he or she can always, without further questions, withdraw from the study, are considered capable of participation.

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Basic science |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 23-07-2019 |
| Enrollment: | 300 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 23-10-2018 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 05-03-2020 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 13-08-2020 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL64868.078.18 |