

# Functional imaging of the locus coeruleus

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

## Summary

### ID

NL-OMON32899

### Source

ToetsingOnline

### Brief title

Imaging the LC

### Condition

- Other condition

### Synonym

nvt

### Health condition

gezonde brein

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universiteit Leiden

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** attention, fMRI, locus coeruleus, noradrenergic

## Outcome measures

### Primary outcome

Brain activation as measured by MRI

### Secondary outcome

N/A

## Study description

### Background summary

Animal research has indicated an important role for the neuromodulatory locus coeruleus\*norepinephrine (LC-NE) system in the optimization of performance and the regulation of the exploration-exploitation tradeoff. There have been very few empirical studies of LC-NE function in humans, in part because of the methodological challenges involved. Recent MRI research has identified a scan sequence that reliably visualizes the LC in individual subjects (Shibata et al., 2008). This has removed the most important obstacle for functional imaging studies of the LC using fMRI.

### Study objective

The primary objective of this study is to understand the functional significance of the human LC-NE system. To this end, we will acquire fMRI data and behavioral responses of 16 healthy adults (aged 18-30 years) in each of three experiments.

### Study design

We will measure functional magnetic resonance imaging (fMRI) signals while subjects respond with button-presses to simple stimulus sequences displayed on

a screen. The effect of task manipulations on fMRI will be assessed.

### **Study burden and risks**

There are no known risks associated with participating in an MRI study. This is a noninvasive technique involving no catheterizations or introduction of exogenous tracers. Numerous children and adults have undergone magnetic resonance studies without apparent harmful consequences. Some people become claustrophobic while inside the magnet and in these cases the study will be terminated immediately at the subject's request. The only absolute contraindications to MRI studies are the presence of metal in the body, like intracranial or intraocular metal, or a pacemaker. Relative contraindications include pregnancy and claustrophobia. Subjects who may be pregnant, who may have any metal in their body will be excluded because of potential contraindications of MRI in such subjects.

Although there is no direct benefit to the participants in the proposed research, there are possible benefits to society from the potential knowledge gained from this study: This study will be the first functional imaging study of human LC function. Our study will clear the way LC functional imaging studies in patient populations known to have disturbed noradrenergic function, which might lead to a better understanding of the pathology.

## **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

Adults subjects (18-30 years of age) with no history of neurological disorder/disease and no counter-indications to MRI will be included in this study. All participants will be right-handed native Dutch speakers with normal vision or contact lenses

### Exclusion criteria

Potential participants will be prescreened for contraindications for fMRI, which include metal implants, heart arrhythmia, claustrophobia, and possible pregnancy. They will additionally be prescreened for head trauma, history of neurological or psychiatric illness and/or use of psychotropic medications. Finally, left-handed individuals will be excluded from the study because some left-handers have substantially different brain organization relative to right-handers.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-07-2010
Enrollment:	48
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-01-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL29341.058.09