

# Hippocampal blood flow and electroconvulsive therapy in depression

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Mood disorders and disturbances NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON29749

### Source

ToetsingOnline

### Brief title

Hippocampal blood flow and electroconvulsive therapy in depression

### Condition

- Mood disorders and disturbances NEC

### Synonym

Depression, Depressive disorder

### 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:** ASL, Depression, electroconvulsive therapy, MRI

## Outcome measures

### Primary outcome

The primary study parameter will be changes in hippocampal blood flow as a result of ECT measured in ml/min/100g

### Secondary outcome

Differences in hippocampal bloodflow between depressed patients and healthy controls measured in ml/min/100mg.

Changes in depression score before and after ECT treatment as measured by means of the Hamilton depression rating scale.

## Study description

### Background summary

Dispite the fact that electroconvulsive therapy (ECT) is one of the most effective psychiatric therapies, we still have little understanding of how and why it works. Recent evidence suggests that changes in regional cerebral bloodflow associated with depression can be reversed through treatment with ECT. Because most of the supporting evidence comes from animal studies, a clinical studies are needed to elucidate the pathophysiology in humans. If we are able to show that ECT can change blood flow associated with depression, then we are closer to understanding the mechanisms involved in the pathophysiology of depression and the effect of ECT on these processes. With time this may lead to better therapies for depression and other psychiatric diseases.

### Study objective

Our aim is to study the effect of ECT on hippocampal blood flow changes associated with depression.

### Study design

Patients meeting the DSM-IV diagnostic criteria for depression will be compared to healthy control subject on the level of their hippocampal blood flow. Within

the patient group the effect of ECT on hippocampal blood flow will be studied. The diagnosis will be based on a structured interview (SCID). To measure the level of depression and the effect of ECT the Hamilton Depression Rating Scale (HDRS) will be used. To measure the hippocampal blood flow Arterial Spin Labelling (ASL) will be used. ALS is a new MRI technique whereby the protons of the arterial water in the feeding vasculature of the brain are magnetically labeled and used as an endogenous tracer.

### **Study burden and risks**

There is no burden outside the investment of time. MRI has been used as a diagnostic, clinical tool for over 20 years now and there are no known associated risks. The invested time for the patients amounts to 3.5 hours and for the healthy controls 2 hours.

## **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

Patients who meet DSM-IV criteria for depressive disorder and meet the Dutch Psychiatric Association criteria for electroconvulsive therapy. Healthy control subjects who do not meet any DSM-IV criteria. Age between 18 and 65.

## Exclusion criteria

Patients who do not meet DSM-IV criteria for depressive disorder. Healthy controls who meet the criteria for a DSM-IV diagnosis. Subjects who have severe cognitive impairments (e.g. vascular or Alzheimers dementia), severe medical conditions (e.g. coronaire heart disease, COPD, diabetes), non removable metal objects. Subjects who are pregnant or lactating.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2006
Enrollment:	90
Type:	Actual

## Ethics review

Approved WMO	
Date:	01-08-2006

Application type:	First submission
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	NL12141.041.06