Epigenetic changes associated with ECT treatment

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An observational study to test whether ECT induces epigenetic alterations of certain genes in blood lymphocytes and whether these alterations are associated with the cognitive side-effects of ECT treatment and the response to the treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON33354

Source
ToetsingOnline

Brief title
epigenetics in ECT treatment

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
depression, memory complaints

Health condition

cognitieve en aandachtsstoornissen en -afwijkingen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognitive function, depression, ECT, epigenetics

Outcome measures

Primary outcome

1. association between the epigenetic changes like DNA-methylation and histone modifications of certain genes in blood lymphocytes and the cognitive side effects of ECT treatment

2. association between the epigenetic changes like DNA-methylation and histone modifications of certain genes in blood lymphocytes and the response to ECT.

The endpoint of the study will be 6 weeks after cessation of the ECT treatment.

Secondary outcome

not applicable

Study description

Background summary

Recent research has suggested that epigenetic factors play a major role in the aetiology and course of many, if not all, psychiatric diseases. However, research evidence on this topic has been sparse since the methodology to investigate epigenetic alterations has only recently been developed. We hypothesize that environmental changes induce epigenetic alterations, measurable in blood lymphocytes, and that these alterations are associated with the aetiopathology of psychiatric symptoms. In this proof-of-principle study, we specifically hypothesize that electroconvulsive therapy (ECT) in patients with a severe depression results in epigenetic alterations such as changes of DNA methylation or histone modifications in certain genes (involved in the aetiopathogenesis of depressive disorder) and that these changes are associated

with response to the treatment.

Study objective

An observational study to test whether ECT induces epigenetic alterations of certain genes in blood lymphocytes and whether these alterations are associated with the cognitive side-effects of ECT treatment and the response to the treatment.

Study design

observational study

Study burden and risks

Nature of burden of participation for the participants is to allow for additional (to standard medical care) venous blood sampling ans saliva sampling for DNA collection, periodic interviews and questionnaires of psychiatric symptoms and consent to subsequent genetic analyses. When possible the additional blood sampling will be minimized, using the peripheral IV line patients will receive for the administration of anaesthetics, to collect blood. When blood sampling is not possible trough the peripheral IV line, the vena puncture necessary for blood sampling is considered a burden for the participant. The short interviews and questionnaires on psychiatric symptoms and cognitive functioning are not expected to pose any burden or risk for the participating subjects; as these are, with some additions, considered part of the standard medical care

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

depressive disorder and eligible for ECT treatment

Exclusion criteria

• age < 18 years and age >65 jaar
• major medical conditions that may interfere with the study procedures: cancer, cerebrovascular disorders, organic psychiatric syndromes, active drug abuse, mental retardation, dementia and other neurodegenerative disorders. Psychopathology will be assesses by a psychiatric interview.
• Illiteracy
• any condition which in the opinion of the (co-) investigator might interfere with the evaluation of the study objectives

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	25-08-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL26735.068.09