Epigenetic factors in IFNα induced depressive symptoms

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A proof-of-principle study to test whether an environmental factor, i.e. here IFNα treatment, induces epigenetic alterations of certain genes in blood lymphocytes and whether these alterations correlate with the severity of psychiatric symptoms, i.e...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31526

Source
ToetsingOnline

Brief title
Epigenetics in IFNα induced depression

Condition

- Hepatic and hepatobiliary disorders
- Mood disorders and disturbances NEC

Synonym
depression, major depressive disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: depression, epigenetics, IFN&alfa, psychiatry

Outcome measures

Primary outcome

Main study parameter: association between the changes in DNA methylation of certain genes in blood lymphocytes and the severity of depressive symptoms during IFNα treatment. Endpoint 8 weeks after cessation of IFNα treatment

Secondary outcome

no

Study description

Background summary

Recent research has suggested that epigenetic factors play major roles 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 is only recently developed. We hypothesize that certain environmental factors result in epigenetic alterations, measurable in blood lymphocytes, and that these alterations are associated with the onset and severity of psychiatric symptoms. In this proof-of-principle study we specifically hypothesize that IFNα treatment (a routine medical treatment for hepatitis patients) results in epigenetic alterations (such as changes of DNA methylation of certain genes) and that these changes correlate with the severity of depressive symptoms.

Study objective

A proof-of-principle study to test whether an environmental factor, i.e. here IFNα treatment, induces epigenetic alterations of certain genes in blood lymphocytes and whether these alterations correlate with the severity of psychiatric symptoms, i.e. here depressive symptoms

Study design

Observational study

Study burden and risks

Burden:
periodical self rating scales on depressive symptoms
periodic bloodsampling of additional 20ml of blood, which occurs when routine clinical care implies blood sampling (i.e. every 4 weeks), and saliva samples

Risks:
Screening/interviewing for depressive symptoms may worsen depressive symptoms. Subjects which develop a depressive disorder are offered psychiatric treatment.

Contacts

Public
Academisch Ziekenhuis Maastricht

DOT 10
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

chronis hepatitis infection
eligible for IFNα treatment

Exclusion criteria

- age < 18 years
- major medical or psychiatric conditions that may interfere with the study procedures: cancer, cerebrovascular disorders, organic psychiatric syndromes, active drug abuse, major mental disorders as schizophrenia, bipolar disorder, mental retardation, dementia and other neurodegenerative disorders
- illiteracy
- any condition which in the opinion of the investigator might interfere with the evaluation of the study objectives

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-08-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2008

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-06-2008
Application type:	Amendment
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	NL21334.068.08