A single dose Levodopa study to balance goal-directed and habitual behavior in schizophrenia

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to assess whether a single-dose of levodopa improves cognitive symptoms and balances goal-directed and habitual behavior.

Ethical review	Approved WMO
Status	Pending
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON39093

Source
ToetsingOnline

Brief title
Single-dose levodopa in schizophrenia

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychotic disorders

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Nuts-Ohra

Intervention

Keyword: levodopa, Schizophrenia

Outcome measures

Primary outcome

cognitive functioning as assessed by a habit formation task and a n-back

working memory task

Secondary outcome

clinical variables as measured by a panss interview and two questionnaires

Study description

Background summary

Schizophrenia encompasses positive, negative and cognitive symptoms. While antipsychotic medication generally alleviates the positive symptoms, negative and cognitive symptoms remain unchanged. And this while the latter seem to be the best predictors for long-term outcome.

Study objective

to assess whether a single-dose of levodopa improves cognitive symptoms and balances goal-directed and habitual behavior.

Study design

double-blind, randomized, placebo-controlled study with a single dose of levodopa in schizophrenic patients

Intervention

Admission of a single dose of Sinemet

Study burden and risks

Overall burden is low. A small risk exists for increasing the positive symptoms. To minimize this risk, the study will be conducted entirely at the

psychiatric ward where the patients are admitted, so that they are under constant supervision.

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

All patients will be recruited from the Psychiatry ward of the Erasmus Medical Center, Rotterdam, and diagnosed according to DSM-IV criteria by a senior psychiatrist Patients will be included if they meet the criteria for schizophrenia. Further inclusion criteria inpatients aged 18-35 years with a diagnosis of schizophrenia, stable on antipsychotic, with illness duration < 5 years

Exclusion criteria

pregnancy, use of psychotropic medication other than benzodiazepines, serious neurological disorders. Subjects will also be excluded when they cannot understand Dutch language sufficiently to understand the purposes and implications of the experiment.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Sinemet
Generic name:	Levodopa/carbidopa
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	02-11-2012

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-04-2013
Application type:	First submission
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
EudraCT	EUCTR2012-002187-27-NL
CCMO	NL40710.078.12