Clozapine in Daily Life: an Experience Sampling Pilot Study

Published: 08-11-2011
Last updated: 28-04-2024

To determine whether changes in affect of patients with schizophrenia occur after starting clozapine.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35815

Source
ToetsingOnline

Brief title
Clozapine in Daily Life

Condition

- Schizophrenia and other psychotic disorders
- Lifestyle issues

Synonym
psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Clozapine, Experience Sampling Method, PsyMate, Subjective Experience

Outcome measures

Primary outcome

Changes in positive and negative affect will be measured by Experience Sampling Method with the PsyMate. Changes in psychopathology and global functioning will be measured with the PANSS, CGI and GAF. Subjective experience during last week will be measured with the SWN questionnaire. Side-effects will be measured by GASS.

Secondary outcome

-

Study description

Background summary

Subjective experience of patients during use of antipsychotics is highly relevant for the course of the disorder. Because of its unique binding affinity to dopaminergic receptors clozapine might have a favourable effect on affect. The Experience Sampling Method (ESM) is a valid method to assess reactivity to stress in daily life. Research with ESM after medication switch is sparse and yet clinically very relevant.

Study objective

To determine whether changes in affect of patients with schizophrenia occur after starting clozapine.

Study design

an open longitudinal study

Study burden and risks

Patients may benefit from participation in this study because it may give them insight into their symptoms and possible side-effects. No risks are involved in this study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 5
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 5
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Eligible for the study are in- and outpatients age 18 to 60, meeting DSM-IV criteria for schizophrenia, schizoaffective or schizophreniform disorder starting treatment with clozapine. Patients that are admitted under authority of the court should also be included, since this group embodies a part of the target group.
Patients should be able to understand the study information and procedures and give informed consent.

Exclusion criteria

- Pregnancy
- Lactating women
- Female subject without adequate contraception
- Known hypersensitivity to clozapine or ingredients used in these tablets
- Narrow-angle glaucoma
- Known neurological or endocrine disease interfering with clozapine treatment
- Myeloproliferative disorder
- Uncontrolled epilepsy
- Paralytic ileus
- Current leukocyte level lower than 3.5 x 109/l
- Current neutrophilic granulocyte level lower than 2.0x 109/l
-Use of: fluvoxamine, carbamazepine, coumarine derivates, cimetidine, ciprofloxacine, erythromycine, citalopram and cytostatica

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL36202.018.11