Capillary versus venous blood sampling for clozapine blood levels: a practice based study comparing patients experiences, measurement outcomes and costs.

Published: 24-09-2020
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Primary objective of the study is to measure patiënt experience of POC testing. Secondary objectives are correlation of POC testingof antipsychotic blood values with those of the Standard (venous) method and to perform a cost-effectiveness analysis...

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

Summary

ID

NL-OMON49486

Source
ToetsingOnline

Brief title
FAst Clozapine blood LEvel test study (FACILE)

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychotic disorder, schizofrenie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Clozapine, Patiënt reported outcomes, Psychotic disorder

Outcome measures

Primary outcome

patients complete questionnaires on their experience using a VAS scale., risks

are negligible (only one extra capillary prick besides

regularly performed venous blood sample drawing) and therefore the burden is

minimal and the study is group related (study can

only be done using these patients groups).

Secondary outcome

Correlation between serum values of clozapine and cost-effectiveness of point

of care testing for clozapine.

Study description

Background summary

Patients who suffer from schizophrenia experience symptoms such as disorganized thinking, hallucinations and delusions, regularly
complicated by abuse of drugs, suicidality and abnormal behavior, including aggressive behaviour. The disease is treated by
antipsychotic drugs. Clozapine is an atypical antipsychotic drug for
treatment-resistant schizophrenia. Clozapine is known as a last
resort treatment option. For its effectivity clozapine has an unique
opportunity among antipsychotic drugs. Clozapine may cause
potentially dangerous side-effects for which intensive monitoring is mandatory, including blood-sample testing. Schizophrenia
patients often experience blood-sample drawings as a part of their package of

symptoms, such as fear or psychotic experiences.
This makes drawing blood samples a challenge. Feasible, simplified, fast and easy clozapine blood level tests are desirable. This
study is the first point of care (POC) clozapine-level test developed for daily practice in the Netherlands. No study has yet described
patiënt experience and costs in an expert clinic in minimal invasive POC antipsychotic drug blood level testing in therapy resistant
schizophrenia in Europe.

Study objective

Primary objective of the study is to measure patiënt experience of POC testing. Secondary objectives are correlation of POC testing
of antipsychotic blood values with those of the Standard (venous) method and to perform a cost-effectiveness analysis.

Study design

This is an cross-sectional explorative pilot study including 30 patients.

Study burden and risks

patients complete questionnaires on their experience using a VAS scale. Risks are negligible (only one extra capillary prick besides
regularly performed venous blood sample drawing) and therefore the burden is minimal and the study is group related (study can
only be done using these patients groups).

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

patients aged 18 years of age or older, receiving clozapine for schizophrenia or schizo-affective disorder, accessible for treatment and follow-up and able (investigated by the treating physician) or willing to participate/giving informed consent for participation in this study.

Exclusion criteria

Patients acutely involuntary admitted to the hospital (In Dutch: Crisismaatregel, former IBS), patients and/or not able or willing to give their informed consent (In Dutch: wilsonbekwaam inzake afweging participatie in dit onderzoek)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2020
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-09-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL74320.058.20