Monitoring Outcomes of Psychiatric Pharmacotherapy

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In the project *Monitoring Outcomes of Pharmacotherapy (MOPHAR), an infrastructure will be created in which - using standardised protocols - longitudinal monitoring data will be collected regarding Routine Outcome Monitoring (ROM), medication usage...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON56043

Source
ToetsingOnline

Brief title
MOPHAR

Condition

- Psychiatric disorders NEC

Synonym
psychiatric diseases

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Drenthe
Source(s) of monetary or material Support: GGZ Drenthe

Intervention

Keyword: adverse effects, efficacy, monitoring, psychiatric pharmacotherapy

Outcome measures

Primary outcome

The efficacy, (cost)effectiveness and safety of psychiatric pharmacotherapy

(after implementation of a monitoring programme):

- monitoring outcomes, such as antropometric examinations, blood parameters,

etc.

- score on psychiatric questionnaires

- patient characteristics such as pharmacogenetics or biomarker levels

- medication usage

Specific primary and secondary study parameters will be determined for each

individual research question.

Secondary outcome

For example time (e.g. duration of psychotropic drug usage, duration of

treatment at the outpatient department), costs, medication adherence, etc.

Study description

Background summary

Psychiatric patients often have somatic comorbidities and other risk factors that render them vulnerable to the diverse and severe side effects of psychiatric pharmacotherapy. In outpatient clinics of institutions of Mental Health Services (MHS; in Dutch: GGZ) in the Netherlands it is suggested that information regarding effectiveness of the prescribed drugs is not routinely collected using standardised monitoring protocols. It therefore is unclear to which extent the drugs used by the patients visiting these outpatient clinics

are prescribed effectively and safely.

Study objective

In the project *Monitoring Outcomes of Pharmacotherapy (MOPHAR), an infrastructure will be created in which - using standardised protocols - longitudinal monitoring data will be collected regarding Routine Outcome Monitoring (ROM), medication usage and monitoring of side effects of psychiatric pharmacotherapy in outpatients at MHS in the Northern-Netherlands, thereby enabling research. Research objectives are:
1 To investigate the association between patient characteristics and outcomes (e.g. efficacy, (cost)effectiveness, profiles of adverse effects) of psychiatric pharmacotherapy. Among others the association between biomarkers/ pharmacogenetic determinants and the prevalence of adverse events of antidepressants will be investigated.
2 To investigate the association between the use of specific psychotropic drugs and adverse outcomes like metabolic abnormalities.

Study design

Prospective observational cohort study.

Study burden and risks

The burden for subjects consists of the collection of the extra blood sample (10 mL). However, since the extra blood sample will be collected from the same venapuncture as the blood sample(s) for medical treatment and the parameters that will be investigated are measured as a part of routine clinical practice, no extra risks are associated with participation in MOPHAR. The questionnaires and computer task pose no additional burden. Treatment of subjects will not be altered as a requirement for participation in MOPHAR research. Results of this research project can be used to improve daily care at the outpatient departments of MHSs.

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

• Visiting an outpatient department of a participating mental health center (first time or follow-up visit);
• Older than 18 years of age;
• Signed informed consent;

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2016
Enrollment:	10000
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	16-12-2014
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	30-11-2015
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	17-06-2019
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	13-11-2023
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22977
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	NL4779
CCMO	NL49698.099.14
OMON	NL-OMON22977