Het monitoren van bijwerkingen van geneesmiddelen op de poliklinieken van GGZ Drenthe/Monitoring of side effects of medication at outpatient departments of Mental Health Services Drenthe

Gepubliceerd: 19-11-2014 Laatst bijgewerkt: 19-03-2025

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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON22977

Bron
Nationaal Trial Register

Verkorte titel
MOPHAR

Aandoening

psychiatrische aandoeningen/psychiatric diseases, metabool syndroom/metabolic syndrome, angststoornissen/anxiety disorders, stemmingsstoornissen/mood disorders

Ondersteuning

Primaire sponsor: GGZ Drenthe
Postbus 30007
9400 RA Assen
Overige ondersteuning: GGZ Drenthe
Postbus 30007

9400 RA Assen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.
Objectives: In the project ‘Monitoring Outcomes of Pharmacotherapy in the Assen Region’ (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 Drenthe, 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

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Study population: All newly referred and current adult patients from outpatient departments of MHS Drenthe, starting with patients from the Mood and Anxiety Disorder team in Emmen.

Main study parameters/endpoints: The efficacy, (cost)effectiveness and safety of psychiatric pharmacotherapy (after implementation of a monitoring programme).

Doel van het onderzoek

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.

In the project ‘Monitoring Outcomes of Pharmacotherapy in the Assen Region’ (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 Drenthe, thereby enabling research to investigate associations between patient characteristics and outcomes (e.g. efficacy, (cost)effectiveness, profiles of adverse effects) of psychiatric pharmacotherapy and associations between the use of specific psychotropic drugs and adverse outcomes like metabolic abnormalities.

Onderzoeksopzet

All patiënts will undergo somatic screening and medication reconciliation at baseline and will be asked to fill in a couple of questionnaires following protocol. Patients will be followed during the rest of their treatment at the outpatient department following specific protocols depending on the psychotropic medication usage.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in MOPHAR research, a subject must meet all of the following criteria:

• Visiting an outpatient department of MHS Drenthe (first time or follow-up visit);

• Older than 18 years of age;

• Signed informed consent;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

In general, there are no exclusion criteria for inclusion in the MOPHAR cohort.

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	10000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56043
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4779
NTR-old	NTR4918
CCMO	NL49698.099.14
OMON	NL-OMON56043

Resultaten