Deployment of dedicated nursing staff to stimulate use of clozapine.

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Delegation of clozapine monitoring tasks to a Nurse Practitioner (condition A) is at least as safe as Treatment As Usual: physicians perform monitoring tasks themselves (condition B).

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20244

Bron
NTR

Verkorte titel
CLOZ-NP

Aandoening

Non-affective psychotic disorder.
Niet-affectieve psychotische stoornis.

Titel: Deployment of dedicated nursing staff to stimulate use of clozapine.

Hypothese: Physicians in teams of Type/Condition A (where they can delegate clozapine monitoring tasks to a Nurse Practitioner) will prescribe clozapine more often than physicians in teams of Type/Condition B (where they should performing monitoring tasks themselves).

Blindering: Single-blind

Primaire uitkomst: Proportion of patients indicated for clozapine (in condition A vs. B) who actually start with this drug.

Bij korte samenvatting: Primary objective: to examine whether a physician will treat more patients (who have an indication for clozapine) with clozapine, if he can delegate weekly monitoring tasks and discussion of common side-effects to a Nurse Practitioner (NP).

Ondersteuning

Primaire sponsor: Rivierduinen, GGZ Leiden, the Netherlands and Maastricht University, the Netherlands.

Overige ondersteuning: GGZ Leiden, Rivierduinen, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1a. Proportion of missed weekly lab exams (white blood cells) in condition A vs. B.
1b. Number of days the lab exams (white blood cells) are delayed, divided by total number of required lab exams in condition A vs. B.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: The antipsychotic drug clozapine is more effective than other antipsychotics. However, it remains underused, most likely because it is more labour-intensive as white blood cells should be monitored weekly during the first 18 weeks. Especially for outpatients, this generates a lot of extra work for the physician (psychiatrist/resident). A recent survey concluded that professionals “perceived the presence of dedicated staff to arrange and monitor the initiation of clozapine in outpatients as the factor that would enable the use of clozapine most”. The exact proportion of patients with Non-Affective Psychotic Disorder (NAPD) in an outpatient setting who should be treated with clozapine is uncertain.
Primairy objective: To demonstrate that delegation of clozapine monitoring tasks to a NP is at least as safe as Treatment As Usual (TAU).
Secundairy objectives: 1. To examine whether collaboration between a physician and a NP is associated with a longer retention of patients on clozapine. 2. To examine whether collaboration between a physician and a NP is associated with a better outcome in patients who start with clozapine. 3. To examine whether a physician will treat more patients (who have an indication for clozapine) with this drug if he can delegate weekly monitoring tasks and discussion of common side-effects to a Nurse Practitioner (NP). 4. To estimate the proportion of outpatients with NAPD for whom clozapine is indicated, by type of indication 5. To examine the difference between condition A and B in promptness and accuracy of treatment of potentially hazardous side-effects.
In this study we will randomize at least 16 teams into 2 conditions: (A) Collaboration in clozapine treatment between physician and NP, versus (B) TAU: physician performs clozapine monitoring himself.

Doel van het onderzoek

Delegation of clozapine monitoring tasks to a Nurse Practitioner (condition A) is at least as safe as Treatment As Usual: physicians perform monitoring tasks themselves (condition B).

Onderzoeksopzet

04-06-2015: Education of physicians and NPs: during one afternoon psychiatrists of the Dutch Clozapine Collaboration Group (www.clozapinepluswerkgroep.nl) educate physicians and NPs of all participating teams about the diagnosis of treatment-resistance and about other indications for clozapine.

Between 04-06-2015 and 01-10-2015: Baseline assessment: The independent researcher, the responsible physician and NP of each team discuss every patient with NAPD to determine if the patient: a. already uses clozapine; b. has used clozapine and has discontinued this drug (justified or unjustified); c. has an indication for clozapine, with information on type(s) of indication; d. has no indication for clozapine.

September 2015: Training of nurse practitioners.

Between 01-10-2015 and 04-02-2017: One–year study period during which eligible patients will start using clozapine or not. Of all patients that start using clozapine, data will be collected during 18 weeks. Since a patient started in the last week of this year should be monitored for 18 weeks, the study will last an extra 4 months (until February 2017).
Sept 2016-jan. 2017: an extra Treatment As Usual group will be created. This group consists of patients from the intervention teams, who have started clozapine before the start of the trial.

Onderzoeksproduct en/of interventie

1. Education of physicians and NPs about indications for clozapine.

2. Physicians and NPs screen all patients in their team for a possible indication for clozapine.
3. Randomization of teams into condition A or B (treatment as usual).

4. Training of NPs from teams in condition A in management of patients on clozapine.

5. One-year study period will be study period of 15 months

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Teams:

- Outpatient teams in which a nurse practitioner participates
Patients:

- Age 18-55

- Diagnosis: non-affective psychotic disorder

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

NA

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	04-06-2015
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-04-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4988
NTR-old	NTR5135
Ander register	- : RTPO 937a

Resultaten

Samenvatting resultaten
None yet