Schizophrenia Termination Of Pharmacotherapy-STOP-trial.

Gepubliceerd: 05-09-2005 Laatst bijgewerkt: 18-08-2022

H0: continuation or cessation of antipsychotic therapy in psychosis free stable first episode patients with a schizophrenic disordermakes no difference with regard to relapse rates or side-effects.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26866

Bron
Nationaal Trial Register

Verkorte titel
STOP-trial

Aandoening

Schizophrenic disorders:
Schizophrenia
Schizophreniform disorder
Schizoaffective disorder

Ondersteuning

Primaire sponsor: Divisie Hersenen
Overige ondersteuning: The Netherlands Organisation for Health Research and Development (ZonMw)
Eli Lilly and company

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Relapse, operationalized as follows:
The reappearance of psychotic symptoms:
1. As measured by an increase in the total score on the PANSS with at least 20%, and the score of 1 of the following PANSS items being more than 3: Delusions (P1), Conceptual disorganisation (P2), Hallucinations (P3) and Suspicion (P6); OR

2. As expressed by the necessity (and actual fact) of an admittance for psychiatric reasons.

Toelichting onderzoek

Achtergrond van het onderzoek

Termination of pharmacotherapy early in the course of schizophrenia will prevent the burden of side effects of chronic usage of antipsychotics. These iatrogenic effects are multiple and severe, the neurological in particular, and eventually occur in the majority of patients treated for schizophrenia. If antipsychotic treatment is discontinued however, these effects are largely reversible. Therefore, the patient suffering from schizophrenia will benefit from medication if this is not associated with an unacceptable excess risk of psychotic relapse. Altough treatment guidelines for schizophrenia recommend disocntinuation in clinically stable first-episode patients, this is hardly supported by any scientific evidence. The current project aims to change that. In a randomised open trial 150 first episode patients will be assigned to either continuation or gradual discontinuation of their medication.
After two years of follow-up all patients will be evaluated for relapse and side effects. The proportion of first-episode ptients in which side effects of antipsychotics can be prevented by safe mecication withdrawal will be estimated rom the relapse risks. Additional analyses focus on potential predictors of successful discontinuation of antipsychotics. In summary, the results of this project will provide data that allow the psychiatrist to prevent side effects of antipsychotics in a more safe and evidence-based way.

Doel van het onderzoek

H0: continuation or cessation of antipsychotic therapy in psychosis free stable first episode patients with a schizophrenic disordermakes no difference with regard to relapse rates or side-effects.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1. The patient continues with taking the antipsychotic medication according to his/her medication schedule at the day of inclusion and continues this schedule for at least 6 months;

2. The patient tapers the antipsychotic medication in minimally 6 and maximally 12 weeks to zero (if possible).

Contactpersonen

Publiek

University Medical Center Utrecht (UMCU),
Division Brain, Department Adult Psychiatry,
Housepost A.01.126, Room A.01.5.04,
Heidelberglaan 100
G. Boonstra
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)30 2507121

Wetenschappelijk

University Medical Center Utrecht (UMCU),
Division Brain, Department Adult Psychiatry,
Housepost A.01.126, Room A.01.5.04,
Heidelberglaan 100
G. Boonstra
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)30 2507121

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Written informed consent obtained after oral and written explanation to the patient and its doctor;

2. Age 16 to 55 years;

3. Treated for at least a year, with antipsychotics, for a first episode of schizophrenia, schizoaffective disorder of schizophreniform disorder before inclusion;

4. Diagnosis code 195.10, 295.20, 295.30, 295.60, 295.70 of 295.40 according to the DSM-IV criteria as assessed at inclusion with the SCID (Structured Clinical Interview for DSM-IV);

5. The patient used antipsychotics for at least 335 days during the last year;

6. All of the last year the patient was in a state of clinical remission, meant is that no clear symptoms of psychosis were observed, operationalized by the lack of a score of more then 3 on the following PANSS-items (Positive AND Negative Syndrome Scale): Delusions (P1), Conceptual disorganisation (P2), Hallucinations (P3) and Suspicion (P6).
Possibly there were still mild rest symptoms of which the patient experienced no hinder in daily functioning;

7. No serious physical disorder;

8. No psychosis during inclusion, as operationalized under item 6;

9. The patient has to be able to understand and undergo the trial procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Judgement of the treating psychiatrist of the patient;

2. The occurrence of a serious physical disease;

3. Withdrawal of the informed consent of the patient;

4. Death of the patient.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	24-07-2002
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-09-2005
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	NL144
NTR-old	NTR179
Ander register	: Projectnumber 2100.0057 ZonMw
ISRCTN	ISRCTN06332944

Resultaten

Samenvatting resultaten
N/A