Schizophrenia Termination Of Pharmacotherapy-STOP-trial.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26866

Source
Nationaal Trial Register

Brief title
STOP-trial

Health condition

Schizophrenic disorders:
Schizophrenia
Schizophreniform disorder
Schizoaffective disorder

Sponsors and support

Primary sponsor: Divisie Hersenen
Source(s) of monetary or material Support: The Netherlands Organisation for Health Research and Development (ZonMw)
Eli Lilly and company

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Changes over 2 years in score on the Positive And Negative Syndrome Scale (PANSS) or subscales;

2. Changes over 2 years in score on the Calgary Depression Rating Scale (CDRS);

3. Changes over 2 years in score on the Global Assessment of Functioning (GAF);

4. Changes over 2 years in score on the Clinical Global Impression scale (CGI);

5. Changes over 2 years in score on the Unified Parkinson Disease Rating Scale (UPDRS);

6. Changes over 2 years in score on the Abnormal Involuntary Movements Scale (AIMS);

7. Changes over 2 years in score on the Barnes Akathisia Rating Scale (BARS);

8. Changes over 2 years in score on the substance abuse module of the Structured Clinical Interview for DSM-IV (SCID-substance module);

9. Changes over 2 years in brain morphology as measured by structural MRI after 0, 6, 12 and 24 months;

10. Changes over 2 years in score in the weight of the patient;

11. Changes over 2 years in score on the compliance of the patient as measured by the Medication Adherence Rating Scale (MARS);

12. Quality of life measured at the end of the study (WHO-QOL-brief);

13. Number of life-events as measured at the end of the study (Life Events Questionnaire);

14. Quality of life and health measured by the RAND-36;

15. Brain morphologic changes in time taking into account antipsychotic medication use.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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).

Contacts

Public

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	24-07-2002
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-09-2005
Application type:	First submission

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
NTR-new	NL144
NTR-old	NTR179
Other	: Projectnumber 2100.0057 ZonMw
ISRCTN	ISRCTN06332944

Study results

Summary results
N/A