

Schizophrenia Termination Of Pharmacotherapy: STOP-trial

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 14/11/2008	Condition category Mental and Behavioural Disorders	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

ZonMw: 2100.0057; NTR179

Study information

Scientific Title

Prevention of iatrogenic neurological impairment in schizophrenic disorders: the Schizophrenia Termination of Pharmacotherapy (STOP) trial

Acronym

STOP trial

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia, schizophreniform disorder, schizoaffective disorder

Interventions

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)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Relapse, operationalised 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

Key secondary outcome(s)

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 magnetic resonance imaging (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

Completion date

01/07/2007

Eligibility

Key inclusion criteria

1. Written informed consent obtained after oral and written explanation to the patient and its doctor
2. Aged 16 to 55 years
3. Treated for at least a year, with antipsychotics, for a first episode of schizophrenia, schizoaffective disorder or schizophreniform disorder before inclusion
4. Diagnosis code 195.10, 295.20, 295.30, 295.60, 295.70 or 295.40 according to the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (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, operationalised by the lack of a score of more than 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 operationalised under item 6
9. The patient has to be able to understand and undergo the trial procedures

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Judgment 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

Date of first enrolment

24/07/2002

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Utrecht

Utrecht

Netherlands

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Sponsor information

Organisation

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Funder Name

Eli Lilly Nederland BV (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration