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Schizophrenia Termination Of Pharmacotherapy: STOP-trial

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre, randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
24/07/2002

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 of schizophreniform disorder before inclusion
4. Diagnosis code 195.10, 295.20, 295.30, 295.60, 295.70 of 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 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 operationalised under item 6
9. The patient has to be able to understand and undergo the trial procedures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

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)

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Sponsor type
Research organisation

Website
http://www.zonmw.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration