Medication strategies in first onset schizophrenia (Mesifos).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24373

Source
Nationaal Trial Register

Brief title
Mesifos

Health condition

Non-affective psychosis (schizophrenia and related disorders DSM-IV).

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen.
Source(s) of monetary or material Support: ZonMw, Stichting Steun, Stichting Diensbetoon, Eli Lilly Nederland b.v.

Intervention

Outcome measures

Primary outcome

Quality of life.

Secondary outcome

1. Symptomatology;

2. Relapse;

3. Side effects;

4. Social functioning;

5. Burden on the family.

Study description

Background summary

Context:

Treatment guidelines for first episode psychosis recommend maintenance treatment for at least one year (APA) or even two years in The Netherlands. These are based on limited evidence since no prospective study yet compared targeted and maintenance treatment in remitted first episode psychosis.

Objective:

To evaluate differential effects of targeted and maintenance treatment strategies in remitted first episode patients.

Design:

After six months of stable remission of positive symptoms patients were randomly and openly assigned to one of the two treatment strategies. Follow-up was eighteen months. Ratings were single-blinded.

Setting:

Seven mental health care organizations with a catchment area of 3.1 million inhabitants,

coordinated by Department of Psychiatry of the University Medical Center Groningen in the Netherlands.

Patients:

Epidemiologically representative cohort of 131 first episode patients, aged 18 to 45 years, with a diagnosis of schizophrenia or related psychotic disorder experiencing six months of stable remission.

Interventions:

Maintenance treatment strategy carried out according to APA-guidelines using mostly low dose atypical antipsychotics. Targeted treatment strategy carried out by gradually tapering dose and discontinuation.

Main outcome measures:

Relapse, psychopathology, side effects, social and vocational functioning, hospitalization and quality of life.

Results:

Twice as many relapses occurred in targeted treatment (43% vs. 21%, P = 0.007) but neither positive or negative symptoms, side effects, social functioning, nor quality of life differed between strategies during follow-up. Patients in targeted treatment also did not spend more days in hospital while they tended to hold a regular job more often at follow-up (35% vs. 17%, P = .06).

Conclusions:

Targeted treatment seems to be a feasible alternative to maintenance treatment in stably remitted first episode patients. Though relapses were more frequent in targeted treatment,

this had no impact on hospitalization or other functional outcome, while medication use was significantly less and vocational functioning tended to be better.

Study objective

Overall research question:

Is there a difference in quality of life between patients with a first psychotic episode, treated with targeted and maintenance treatment?

Detailed questions:

1. Do both treatment strategies differ with respect to quality of life, subjectively as well as objectively, regarding work, daily activities, housing, social network, satisfaction and wellbeing, including (para)suicide, aggressive behaviors towards others, contacts with police, days in jail), and to social role functioning?

2. Do both treatment strategies differ with respect to the course of the illness (relapse, quality of remission), side-effects of medication (dyskinesia, EPS, subjective well-being), and dependence on care facilities (including involuntary admission)?

3. Does the psychosocially oriented treatment lead to better compliance and earlier recognition of prodromal signs with the possibility of prevention of full blown psychosis by targeted pharmacological treatment?

4. Can we identify predictors of successful drug withdrawal/discontinuation?

5. To what extent are these treatment strategies acceptable to this patient population?

6. To what extent do early drop out and refusal make a difference with respect to mental health care consumption and social outcome?

7. Do direct medical costs differ between the two strategies?

8. Is there a difference regarding indirect costs and burden on the family?

Study design

N/A

Intervention

Maintenance treatment was carried out according to the guidelines of the APA. This entailed

the preferred use of second-generation antipsychotics in low dose.
In targeted treatment the dose was gradually tapered in one or two months and discontinued, if possible. Tapering was allowed to be more gradual, subject to symptom levels and individual preferences of patients. If early warning signs of relapse emerged or positive symptoms recurred, clinicians were to reinstate or increase the dose of antipsychotic medication, not only in targeted, but also in maintenance treatment. If feasible and considered safe, in targeted treatment discontinuation was tried again.

Contacts

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Eligibility criteria

Inclusion criteria

1. Suffering from a first episode of psychosis;

2. Being 18- 45 years of age;

3. Being treatment naïve;

4. Responding to medication (remission of positive symptoms) within 6 months and remaining stable for another 6 months.

Exclusion criteria

No remission or relapse within 6 months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2001
Enrollment:	131
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
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	NL336
NTR-old	NTR374
Other	: DO 0945-01-001
ISRCTN	ISRCTN16228411

Study results

Summary results
Acta Psychiatr Scand. 2006 Apr;113(4):332-9.