

Medication strategies in first onset schizophrenia (Mesifos)

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/07/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

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
NTR374; DO 0945-01-001

Study information

Scientific Title

Acronym

Mesifos

Study objectives

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?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised open label 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

Non affective psychosis, schizophrenia

Interventions

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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Quality of life

Secondary outcome measures

1. Symptomatology
2. Relapse
3. Side effects
4. Social functioning
5. Burden on the family

Overall study start date

01/08/2001

Completion date

01/08/2005

Eligibility

Key inclusion criteria

1. Suffering from a first episode of psychosis
2. 18-45 years of age
3. Treatment naïve
4. Responding to medication (remission of positive symptoms) within 6 months and remaining stable for another 6 months

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Both

Target number of participants

131

Key exclusion criteria

No remission or relapse within 6 months

Date of first enrolment

01/08/2001

Date of final enrolment

01/08/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Centre Groningen (UMCG) (Netherlands)

Sponsor details

Hanzeplein 1

Groningen

Netherlands

9713 GZ

Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl/azg/nl/english/azg/>

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Industry

Funder Name

Eli Lilly B.V. (Netherlands)

Funder Name

Service Foundation (Stichting Diensbetoon) (Netherlands)

Funder Name

Support Foundation (Stichting Steun) (Netherlands)

Funder Name

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

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2006		Yes	No
Results article	results	01/09/2013		Yes	No