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Medication strategies in first onset schizophrenia (Mesifos)

Submission date	Recruitment status	[ ] Prospectively registered
19/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/07/2013	Mental and Behavioural Disorders	

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