'Effectiveness of Penfluridol (long acting neuroleptic) as compared to second generation oral neuroleptics (olanzapine and risperidone) in psychotic disorder patients: an open label randomized controlled trial'

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26965

Source
Nationaal Trial Register

Health condition

psychotic disorder
medication compliance
penfluridol
olanzapine
risperidone

Sponsors and support

Primary sponsor: Erasmus University Medical Center, Rotterdam
Psychiatry Department
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

time to all-cause medication discontinuation

Secondary outcome

- healthcare related costs

- quality of life

- reason for treatment discontinuation

- efficacy

- safety and tolerability

- drug attitude

- subjective well-being

- insight

Study description

Background summary

The aim of this study is to determine the long-term effectiveness and tolerability of penfluridol (acemap; oral long acting neuroleptic) and second generation oral neuroleptics (olanzapine, risperidone) using an open label randomized controlled trial design in 180 patients. One group receives penfluridol once weekly, one group receives onlanzapine once daily and the other group receives risperidone once daily as prescribed by the treating clinician, according to current conventional care, based on prescribed guidelines. The main study parameter will be time to all-cause medication discontinuation. Secondary endpoints include the reason for treatment discontinuation, efficacy, safety and tolerability, drug attitude, subjective well-being, insight, health care related costs and quality of life.

Study objective

We hypothesize that penfluridol as compared to oral second generation neuroleptics

(olanzapine and risperidone), will show better compliance (primary outcome) and therefore lower healthcare costs.

Study design

- for primary outcome: 0,24,6,8,10,12 weeks, 6,9,12 months
- for secondary outcomes: 0,3,12 months

Intervention

comparison of (adherence of) two daily oral antipsychotics (olanzapine and risperidone) to a weekly oral antipsychotic (penfluridol)

Contacts

Public
Prins Constantijnweg 48-54
C.L. Mulder
Erasmus MC, Research Center O3
Rotterdam 3066 TA
The Netherlands
+31 (0)6 27034001
Scientific
Prins Constantijnweg 48-54
C.L. Mulder
Erasmus MC, Research Center O3
Rotterdam 3066 TA
The Netherlands
+31 (0)6 27034001

Eligibility criteria

Inclusion criteria

1. age 18-65 years

2. psychotic disorder, including schizophrenia, schizoaffective disorder, delusional disorder or psychosis not otherwise specified

3. treatment on an outpatient basis or inpatient treatment followed by outpatient care (expected duration of admission less than 6 weeks)

4. psychiatrist treating the patient decides that it is appropriate (based on clinical judgement, guidelines, history and symptoms of the patient) to prescribe either penfluridol, olanzapine or risperidone and that there are no decisive contra-indications

5. patient is willing to use oral neuroleptic treatment, including penfluridol, olanzapine or risperidone

6. able to give informed consent

Exclusion criteria

1. judicial order stating that taking medication is obliged

2. patient did use penfluridol during the previous six months

3. serious and unstable medical condition

4. insufficient proficiency in Dutch language

5. women who are pregnant

6. patient is on adequate antipsychotic therapy

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2017
Enrollment:	180

Type:	Anticipated

Ethics review

Positive opinion Date:	28-12-2016
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	NL6021
NTR-old	NTR6152
Other	NL51189.078.14 : 2014-003834-21

Study results

Summary results

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