'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'

Gepubliceerd: 28-12-2016 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26965

Bron
Nationaal Trial Register

Aandoening

psychotic disorder
medication compliance
penfluridol
olanzapine
risperidone

Ondersteuning

Primaire sponsor: Erasmus University Medical Center, Rotterdam
Psychiatry Department

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

time to all-cause medication discontinuation

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-12-2016

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6021
NTR-old	NTR6152
Ander register	NL51189.078.14 : 2014-003834-21

Resultaten

Samenvatting resultaten

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