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Subjective well-being, craving for Cannabis and compliance or medication switch in a randomised double blind study with Olanzapine and Risperidone

Submission date
16/05/2005

Recruitment status
No longer recruiting

Registration date
16/05/2005

Overall study status
Completed

Last Edited
07/01/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Protocol serial number
NTR28

Study information

Scientific Title
Subjective well-being, craving for Cannabis and compliance or medication switch in a randomised double blind study with Olanzapine and Risperidone

Acronym
SUB.CAN.OLA.RIS

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, parallel group, double-blinded trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia, schizo-affective disorder, schizofreniform disorder

Interventions
Patients are treated double blind with olanzapine (5 - 20 mg) or risperidone (1.25 - 5 mg) for six weeks. At t = 0, t = 7 days and t = 42 days, questionnaires are taken and after six weeks the medication is disclosed. The physician and patient decide if this neuroleptic will be continued. After one year the questionnaires are taken once more.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Olanzapine and risperidone

Primary outcome(s)
1. Subjective Well-Being Under Neuroleptics Scale (SWN)
2. Obsessive Compulsive Drug Use Scale (OCDUS)
3. Positive And Negative Symptoms Scale (PANSS) based on information from the semi-structured interview (SCI-PANSS)

4. Calgary Depression Rating Scale (CDRS)
5. Extra-Pyramidal Symptom Rating Scale (ESRS)
6. Clinical Global Impression (CGI)
7. Yale Brown Obsessive Compulsive Scale (Y-BOCS)
8. Desires for Drugs Questionnaire (DDQ)
9. Drug Use Self Report (DUSR)
10. Recent Drug Use Urinalysis (RDUU)

Key secondary outcome(s))
1. Drop out from the study
2. Medication compliance and medication switch, symptoms and rehospitalisations during one year follow up, measured with the Life Chart Schedule (LCS)

Completion date
01/07/2007

Eligibility

Key inclusion criteria
1. Patients should be able to understand the study description and give informed consent
2. Diagnosis of schizophrenia, schizoaffective disorder or schizophreniform disorder according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)
3. Patients experience a first or second psychotic episode
4. Age is between 18 and 30 years
5. No current use of clozapine
6. Patients must be reliable. They must agree to co-operate with all tests and examinations required by the protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
128

Key exclusion criteria
1. Pregnancy
2. Lactating women
3. Female subject without adequate contraception

4. Known hypersensitivity to any ingredient of olanzapine or risperidone
5. Concomitant use of any other antipsychotic drug than olanzapine or risiperidone
6. Patients are not allowed to have received depot anti-psychotics for a period of at least three months prior to the study
7. Use of other psychotropic medication other than oxazepam or biperiden
8. Narrow-angle glaucoma
9. Known neurological or endocrine disease

Date of first enrolment
01/07/2003

Date of final enrolment
01/07/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 BC

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Eli Lilly (The Netherlands)

Results and Publications

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	01/06/2008	07/01/2021	Yes	No