

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	☐ Prospectively registered
Registration date 16/05/2005	Overall study status Completed	☐ Protocol
Last Edited 07/01/2021	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 risperidone
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