Subjective well-being, craving for cannabis and compliance or medication switch in a randomized doubleblind study with olanzapine and risperidone.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22184

Source
Nationaal Trial Register

Brief title
SUB.CAN.OLA.RIS

Intervention

Outcome measures

Primary outcome

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. ESRS: Extra pyramidal Symptom Rating Scale;

6. Clinical Global Impression (CGI);

7. Y-BOCS (Yale Brown Obsessive Compulsive Scale);

8. Desires for Drugs Questionnaire (DDQ);

9. Drug Use Self Report (DUSR);

10. Recent Drug Use Urinalysis (RDUU).

Secondary outcome

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).

Study description

Background summary

N/A

Study objective

N/A

Study design

N/A

Intervention

Patients are treated double blind with olanzapine (5-20 mg) or risperidone (1,25-5 mg) for 6 weeks. At t=0, t=7 days and t=42 days, questionnaires are taken and after 6 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.

Contacts

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Eligibility criteria

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 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.

Exclusion criteria

1. Pregnancy;

2. Lactating women;

3. Female subject without adequate contraconception;

4. Known hypersensitivity to any ingredient of olanzapine or risperidone;

5. Concomitant use of any other antipsychotic drug than olanzapine or rsiperidone;

6. Patients are not allowed to have received depot- antipsychotics for a period of at least 3 months prior to the study;

7. Use of other psychotropic medication other than oxazepam or biperideen;

8. Narrow-angle glaucoma;

9. Known neurological or endocrine disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2003
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	22-11-2004
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	NL4
NTR-old	NTR28
Other	: N/A
ISRCTN	ISRCTN46365995

Study results

Summary results
N/A