

Efficacy and tolerability of ziprasidone versus clozapine in the treatment of dually diagnosed (DD-) patients with schizophrenia and cannabis use disorder: a randomised study

Submission date 07/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/01/2006	Overall study status Completed	☐ Protocol
Last Edited 01/09/2021	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
Prof Euphrosyne Gouzoulis-Mayfrank

Contact details
University of Cologne
Department of Psychiatry and Psychotherapy
Kerpener Str. 62
Cologne
Germany
50937
+49 (0)221 478 4825
e.gouzoulis@uni-koeln.de

Additional identifiers

Protocol serial number
EXPSY 0105

Study information

Scientific Title

Efficacy and tolerability of ziprasidone versus clozapine in the treatment of dually diagnosed (DD-) patients with schizophrenia and cannabis use disorder: a randomised study

Study objectives

Nearly 50% of schizophrenic patients fulfill the criteria of a coexisting substance abuse /dependence. Cannabis is the number one within the illicit drugs. It is shown that cannabis-abuse is associated with higher rates of relapse, less compliance with the therapy and high rates of suicidal behaviour.

Hypothesis:

Patients with schizophrenia and cannabis abuse/dependency who are randomised to ziprasidone (ziprasidone group) do not use cannabis more frequently and/or more heavily than patients who are randomised to clozapine (clozapine group).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study received approval from the Ethics Committee on 01/12/2005.

Primary study design

Interventional

Study design

Open, randomised, controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

Patients will be randomised to either the ziprasidone or clozapine group. After 3, 6 and 12 months, we evaluate the possible effects on the course of schizophrenia and the consumption of cannabis. Moreover, all patients will get psychiatric/psychotherapeutic and sociorehabilitative elements.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ziprasidone, Clozapine

Primary outcome(s)

1. Amount of cannabis consumption 12 months after inclusion in the study
2. Less side effects in ziprasidone group
3. After 12 months:
 - 3.1. Better compliance in ziprasidone group
 - 3.2. Better course of schizophrenia within the ziprasidone group

Key secondary outcome(s)

1. Amount of cannabis consumption 3 and 6 months after inclusion in the study
2. Others compared with primary outcomes just to 3 and 6 months

Completion date

01/01/2009

Eligibility**Key inclusion criteria**

1. Patients with schizophrenia, schizophreniform or schizoaffective disorder according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (295.xx) and International Statistical Classification of Diseases and Related Health Problems - tenth revision (ICD-10) (F20, F23.2, F25) as well as cannabis abuse or dependence according to DSM-IV (305.20, 304.30) and ICD-10 (F12.1, 12.2)
2. Capable of giving written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Other relevant neuropsychiatric disorders
2. Prominent (acute) positive symptoms at the timepoint of inclusion
3. Previous treatments with ziprasidone or clozapine with significant side effects
4. No availability of a family member or significant other for the collateral interviews of the follow-up evaluation
5. No compliance with the requirements of the study/lack of or questionable capability of giving informed consent

Date of first enrolment

01/01/2006

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

Germany

Study participating centre

University of Cologne

Cologne

Germany

50937

Sponsor information

Organisation

University of Cologne (Germany)

ROR

<https://ror.org/00rcxh774>

Funder(s)

Funder type

Industry

Funder Name

Pfizer Pharma GmbH (Germany)

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](#)

15/03/2014

01/09/2021

Yes

No