ISRCTN27750123 https://doi.org/10.1186/ISRCTN27750123

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

Registration date
20/01/2006

Overall study status
Completed

Last Edited
01/09/2021

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
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.

Study design
Open, randomised, controlled study

Primary study design
Interventional

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