ISRCTN42412532 https://doi.org/10.1186/ISRCTN42412532

Treatment Of Cognitive deficits in schizophrenia with Tolcapone And Pergolide

Submission date	Recruitment status	[ ] Prospectively registered
10/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/04/2010	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michael Paulzen

Contact details
Universitätsklinikum Aachen
Klinik für Psychiatrie und Psychotherapie
Pauwelsstr. 30
Aachen
Germany
52074

Additional identifiers

Protocol serial number
2008-006905-18

Study information

Scientific Title
Pharmacotherapy of cognitive deficits in schizophrenic disorders: a randomised placebo-controlled double-blind study of tolcapone versus pergolide

Acronym

TOCTAP

Study objectives
Cognition in patients with schizophrenia is enhanced using pro-cognitive drugs like pergolide or tolcapone compared to placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty RWTH Aachen University approved on the 14th January 2010

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia, cognitive functions

Interventions
TOCTAP is a randomised, three-armed double-blind study with 60 patients suffering from schizophrenia, using DSM-IV diagnostic criteria. Patients are randomised in three groups of 20 patients each. Patients either receive 300 mg of tolcapone (100 mg - 100 mg - 100 mg) or 0.30 mg of pergolide (0.25 mg - 0.05 mg - 0.00 mg) or placebo three times daily (TID). Cognitive function is tested using the MATRICS Consensus Cognitive Battery (MCCB) at baseline and after a period of six weeks of pro-cognitive medication.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Pergolide, tolcapone

Primary outcome(s)
Change in Matrics Consensus Cognitive Battery (MCCB), tested at baseline and after a treatment period of six weeks

Key secondary outcome(s))
Improvement of clinical outcome regarding schizophrenic symptoms, tested at baseline and after a treatment period of six weeks

Completion date

01/10/2011

Eligibility

Key inclusion criteria
1. 60 patients suffering from schizophrenia using Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria
2. Signed informed consent
3. Aged 18 - 55 years, either sex
4. Negative pregnancy test
5. No drug addiction
6. No suicidality
7. Ability to understand and read German language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Drug addiction
2. Severe medical problems
3. Long-QT-syndrome
4. Problems regarding the heart-valves
5. Seizures
6. Reduced liver or renal function
7. Pregnancy
8. Known incompatibility of the study-drugs

Date of first enrolment
01/04/2010

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
Germany

Study participating centre
Universitätsklinikum Aachen
Aachen
Germany
52074

Sponsor information

Organisation
RWTH Aachen University (Germany)

ROR
https://ror.org/04xfq0f34

Funder(s)

Funder type
Research council

Funder Name
RWTH Aachen University (Germany) - funding from local medical faculty

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes