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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
Improvement of clinical outcome regarding schizophrenic symptoms, tested at baseline and after a treatment period of six weeks

Overall study start date
01/04/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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)

Sponsor details
represented by the CTC-A (clinical trials centre Aachen)
Pauwelsstrasse 30
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Sponsor type
University/education

Website
http://www.ctc-a.de

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration