

Treatment Of Cognitive deficits in schizophrenia with Tolcapone And Pergolide

Submission date 10/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/04/2010	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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

Aachen

Germany

52074

ctc-a@ukaachen.de

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