Trial Description

Title

A randomized double-blind controlled trial to assess the benefits of olanzapine and amisulpride combination treatment in acutely ill schizophrenia patients.-COMBINE

Trial Acronym

Combine-study

URL of the trial

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Brief Summary in Lay Language

Patients acutely ill with schizophrenia or schizoaffective psychosis can be treated within this study. Background of this trial is, that some patients treated with a single antipsychotic compound still suffer from psychotic symptoms. Therefore many patients are treated with several antipsychotic drugs in routine care. But up to now it is not scientifically proven that the combination treatment of two or more antipsychotic drugs is better than the therapy with only one drug. Therefore this trial compares three different treatment options: 1. the antipsychotic combination treatment of olanzapine and amisulpride, 2. olanzapine + placebo monotherapy, 3. amisulpride + placebo monotherapy.

Brief Summary in Scientific Language

Objective of the trial is to find a rationale for the antipsychotic combination therapy. For this reason the therapeutic efficiency and the occurence of adverse drug reactions in combination therapy shall be examined using the example of amisulpride and olanzapine combination therapy compared to amisulpride and olanzapine monotherapy in acutely ill schizophrenia patients. The hypothesis is that patients with combination treatment show higher improvement on the Positive and Negative Symptom Scale (PANSS) after 8 weeks.

Organizational Data

- DRKS-ID: **DRKS00003603**
- Date of Registration in DRKS: **2012/05/18**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **MC-LKP-563 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

- EudraCT-No. (for studies acc. to Drug Law): **2011-002463-20**
- BfArM-No.: **4038052**

Health condition or Problem studied

- ICD10: **F20 - Schizophrenia**
- ICD10: **F25 - Schizoaffective disorders**

Interventions/Observational Groups

- Arm 1: **amisulpride 400-800 mg/d + olanzapine 10-20 mg/d for 16 weeks**
- Arm 2: **amisulpride 400-800 mg/d + Placebo for 16 weeks**
- Arm 3: **olanzapine 10-20 mg/d + Placebo for 16 weeks**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

change of the PANSS total score, which shows the efficiency of treatment by reduction of acute positive and negative symptoms, from baseline to treatment week 8.

Secondary Outcome

- PANSS total score reduction from baseline to week 16.
- PANSS total score reduction from baseline to every 2 weeks up to week 16.
- PANSS total score reduction from baseline to week 2 as predictor of the change

after 8 weeks
- change of the clinical condition measured every 2 weeks by CGI from baseline up to week 16.
- change of the subjective well-being under therapy measured by the SWN scale between week 0, 8, 16.
- Frequency and severity of serious adverse drug reactions

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **LVR-Klinikum Düsseldorf, Düsseldorf**
- Medical Center **LVR-Klinik Langenfeld, Langenfeld**
- Medical Center **LVR-Klinik Köln, Köln**
- University Medical Center **Universitätsklinikum Leipzig, Leipzig**
- Medical Center **Bezirksklinikum Regensburg, Regensburg**
- University Medical Center **Klinik für Psychiatrie, Psychotherapie und Psychosomatik, Aachen**
- Medical Center **Bezirkskrankenhaus Augsburg, Klinik für Psychiatrie, Psychotherapie und Psychosomatik, Augsburg**
- University Medical Center **Psychiatrische Klinik der Ludwig-Maximilians-Universität, München**
- Medical Center **Zentralinstitut für Seelische Gesundheit Mannheim, Klinik für Psychiatrie und Psychotherapie , Mannheim**
- Medical Center **Rheinhessen Fachklinik Alzey, Alzey**
- Medical Center **LWL Klinik Dortmund, Dortmund**
- University Medical Center **Universitätsmedizin Göttingen - Klinik für Psychiatrie und Psychotherapie, Göttingen**
- Medical Center **Rheinmosel Fachklinik Andernach, Andernach**
- Medical Center **Zentrum für Seelische Gesundheit, Kreisklinik Groß-Umstadt, Groß-Umstadt**
- University Medical Center **Medizinische Hochschule Hannover, Hannover**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/06/15**
- Target Sample Size: **399**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

Patients with schizophrenia and schizoaffective disorder according to ICD-10; age 18-65 years; Positive and Negative Symptom Scale Total-Score ≥ 70 and two items of the positive symptom subscale ≥4; voluntary treatment after written informed consent; legal capacity; patients being able and willing to follow study procedures according to the protocol (i.e. sufficient knowledge of German language); exclusion of pregnancy by laboratory test (Beta HCG)

Exclusion criteria

**participation in other interventional studies with drugs or medical devices; first episode patients; physical disease that might have effects on the conduct or evaluation
of the tria; contraindications to medication according to experts information; oversensitivity to active substance or other component of the drugs used; known clozapin resistance; suicidal ideation; pregnancy or lactation; wish of pregnancy or absence of save contraception; dependency to sponsor or investigator; institutionalization through judicial or regulatory order; oversensitivity to placebo (Mannit/Aerosil)**

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*