PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Agitation, aggression and arrousal in patients suffering from psychosis - comparison parenteral benperidol, ziprasidone and aripiprazole

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Investigation on efficacy, tolerance and acceptance of treatment with parenteral benperidol, aripiprazol and ziprasidone in patients suffering from schizophrenia (ICD10: F20) or schizoaffective disorder (ICD10: F25) in episodes of aggression.

Brief Summary in Scientific Language

Psychosis patients often suffer from agitation and aggression when exacerbated. This causes difficulties in the treatment of such patients. Treatment of acute exacerbations of psychosis with agitation and/or aggression is often accompanied by a malcompliance. To avoid aggression and assaults to the patient or other individuals a rapidly occuring effect of the chosen pharmacotreatment is needed. Therefore, antipsychotics in addition to sedatives are the first choice of treatment. In a number of patients the chosen drugs have to be applicated by parenteral formules.
There are two high potential first generation antipsychotics (haloperidole, benperidole) which are often used as first line treatment in high doses. This treatment is accompanied with a high incidence of sideeffects. Beside the desired reduction of aggression and agitation, extrapyramidale motoric symptoms (EPMS) like dyskinesia, rigidity or tremor as well as sedation can be observed regularly. These sideeffects often cause a malcompliance in the acute phase of treatment as well as in the maintenance of rtreatment response.

Atypical antipsychotics are characterized by a better acceptance due to a differing side profile with a lower incidence of EPMS.
To date, aripiprazole and ziprasidone can be applicated parenterally.

After the acute phase with stabilisation of the psychotic exacerbation a long term treatment for the maintenance of the stabilisation is needed. Due to the sideeffect profiles the German society of psychiatry and psychotherapy (DGPPN) recommends atypical antipsychotics to be used in the treatment of psychosis.
If classical antipsychotics are used in the acute phase of psychosis a change of drugtreatment has to be done according to the guidlines of the DGPPN. This may cause uncertanties in patients. Additionally, the change of treatment can lead to a

destabilisation of the patients as it it not warranted that the chosen atypical antipsychotic drug is effective enough.

In this study, we compare the efficacy, sideffects as well as the acceptance of patients of parenterally treatment with either benperidole as a representative of the classical antipsychotics or aripiprazole and ziprasidone as atypical antipsychotics.

Organizational Data

- DRKS-ID: **DRKS00004620**
- Date of Registration in DRKS: **2013/01/21**
- 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.: **2012184 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **benperidole**
- Arm 2: **intramuscular aripiprazole**
- Arm 3: **intramuscular ziprasidone**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
-

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Non-randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control (effective treament of control group)**

- Purpose: **Other**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

1. Change of BPRS
2. Change of positive and negative syndrome scale - excited component

Secondary Outcome

1. total number of parenteral injections
2. duration of parenteral incejtions in days
3. duration of treatment in hospital after last parenteral injection
4. dose of sedatives given to patients in chlorpromazin equivalents
5. side effects and acceptance rated by UKU Rating Scale
6. acceptance of patients the day after the last injection by visual analog scale

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **LVR-Klinik Köln, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/10/01**
- Target Sample Size: **90**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2012/10/01**

Target Sample Size: **90**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

diagnosis (ICD10) of schizophrenia (F20) or schizoaffective disorder (F25)

BPRS of at least 12 points
age of 18 up to 65 years
written informed consent on participation to the study

Exclusion criteria

Patients which do not fullfill the criteria (ICD10) for schizophrenia or schizoaffective disorder.
Age under 18 or over 65 years.
A BPRS of lower then 12 points.

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

LVR-Klinik Köln

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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URL: **[---]***

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.*