

Trial Description

Title

Evaluation of the attitude of patients suffering from psychiatric disease and staff personal in psychiatric hospitals regarding clinical studies underlying the German Drug law.

Trial Acronym

EPMSA

URL of the trial

[---]*

Brief Summary in Lay Language

Introduction:

Often, it is difficult to include patients into clinical studies underlying the German Drug Law (GDL). Several factors have been detected to have an impact to recruitment in studies. Looking for recruitment to psychiatric studies there is poor evidence for factors influencing recruitment.

Aim of the study:

Patients suffering from psychotic or depressive disorders as well as medical staff are included to investigate several clinical and epidemiological factor which might have an impact on the attitude to clinical studies.

Hypothesis:

- 1. Physicians and nurses have got a different attitude to clinical studies underlying the GDL.**
- 2. Patients with depressive disorder differ in the attitude to clinical studies underlying the GDL compared with patients suffering from psychotic disorder.**
- 3. The severity of the disease is correlated with the attitude to clinical studies underlying the GSL.**

Method:

Participants to the study will be asked to fulfill a questionnaire which was conducted for the study. The questionnaire is composed of validated items from somatic studies and of items specific for psychiatric diseases. Scores are correlated to different clinical and epidemiological factors. Additionally, patientgroups (psychotic vs. affective disorder, F20 and F25 vs. F32 and F33) and medical staff (physicians and nurses) are compared to each other.

Brief Summary in Scientific Language

Introduction:

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Method:

One time only, participants to the study will be asked to fulfill a questionnaire which was conducted for the study. The questionnaire is composed of validated items from somatic studies and of items specific for psychiatric diseases. Scores are correlated to different clinical and epidemiological factors. Additionally, patientgroups (psychotic vs. affective disorder, F20 and F25 vs. F32 and F33) and medical staff (physicians and nurses) are compared to each other.

Organizational Data

- DRKS-ID: **DRKS00009619**
- Date of Registration in DRKS: **2015/11/05**
- 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.: **2015320 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs**Health condition or Problem studied**

- ICD10: **F20 - Schizophrenia**
- ICD10: **F25 - Schizoaffective disorders**
- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**

Interventions/Observational Groups

■ Arm 1: Patientgroup 1:

Patients which are included suffer from depressive disorder (ICD10: F32.*) or recurrent depressive disorder (ICD10: F33.*).

Age from 18 to 65 years

Patients must stay voluntary in psychiatric hospital when included into the study.

Aim of the study is to investigate factors which might have an impact on recruitment to studies underlying the GML. This is of interest as in a lot of psychiatric studies underlying the GML recruitment is difficult

One-time-only, patients are asked to fulfill a questionnaire which assesses the attitude of different groups of patients suffering from psychiatric diseases. Several factors, which might have an impact on recruitment to studies underlying the GML, are analysed.

Additionally, the severity of the psychiatric disease and the compliance is correlated to the attitude of patients.

■ Arm 2: Patientgroup 2:

Patients which are included suffer from Schizophrenia (ICD10: F20.*) or schizoaffective disorder (ICD10: F25.*).

Age from 18 to 65 years

Patients must stay voluntary in psychiatric hospital when included into the study.

Aim of the study is to investigate factors which might have an impact on recruitment to studies underlying the GML. This is of interest as in a lot of psychiatric studies underlying the GML recruitment is difficult

One-time-only, patients are asked to fulfill a questionnaire which assesses the attitude of different groups of patients suffering from psychiatric diseases. Several factors, which might have an impact on recruitment to studies underlying the GML, are analysed.

Additionally, the severity of the psychiatric disease and the compliance is correlated to the attitude of patients.

■ Arm 3: medical staff group 1:

Medical staff personal in psychiatric hospital will be included. Staff personal must belong to the occupation group of nurses (state qualified nurse, trained nurse or nurse in training)

In the study, we investigate the attitude of nurses in psychiatric hospital to studies underlying the GML. This is of interest, as it is difficult to win approval of patients to participate in psychiatric GML-studies. Nurses are confidential persons to psychiatric patients.

A positive attitude of nurses to GML-studies may have an impact on recruitment of patients in GML-studies. It is of interest to understand factors which have an impact on the attitude of nurses. This can be used to gain nurses support in recruitment in GML-studies.

One-time-only, nurses are asked to fulfill a questionnaire which assesses the attitude to GML-studies. Several factors, which might have an impact on recruitment to studies underlying the GML, are analysed. The extracted factors are compared with the attitude of physicians in psychiatric hospitals.

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One-time-only, nurses are asked to fulfill a questionnaire which assesses the attitude to GML-studies. Several factors, which might have an impact on recruitment to studies underlying the GML, are analysed. The extracted factors are compared with the attitude of physicians in psychiatric hospitals.

■ Arm 4: medical staff group 2:

Medical staff personal in psychiatric hospital will be included. Staff personal with state examination in human medicine.

In the study, we investigate the attitude of physicians in psychiatric hospital to studies underlying the GML. This is of interest, as it is difficult to win approval of patients to participate in psychiatric GML-studies. Physicians are confidential persons to psychiatric patients.

A positive attitude of physicians to GML-studies may have an impact on recruitment of patients in GML-studies. It is of interest to understand factors which have an impact on the attitude of physicians. This can be used to gain physicians support in recruitment in GML-studies.

One-time-only, physicians are asked to fulfill a questionnaire which assesses the attitude to GML-studies. Several factors, which might have an impact on recruitment to studies underlying the GML, are analysed

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The staff personal groups "physicians" and "nurses" are asked to fulfill one-time-only the questionnaire.

Primary endpoint:

Group comparison of the sum score in the questionnaire "Attitude of physicians and careers to clinical studies underlying the GML".

Secondary Outcome

Both patientgroups are asked to fulfill one-time-only the questionnaires "Attitude of patients suffering from psychiatric diseases to clinical studies underlying the GML" and the "DAI-10", German version.

Hypothesis 2:

Groupcomparison of patientgroup 1 and patientgroup 2. Sumscore of the questionnaire "Attitude of patients suffering from psychiatric diseases to clinical studies underlying the GML".

Hypothesis 3:

Evaluation of the sumscore of the questionnaire "Attitude of patients suffering from psychiatric diseases to clinical studies underlying the GML" and sumscore of the questionnaire "DAI-10", German version.

- **Correlation of both sumscores in patientgroup 1.**
- **Correlation of both sumscores in patientgroup 2.**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- **Medical Center LVR-Klinik Köln, Köln**
- **University Medical Center LVR-Klinik und Kliniken der Heinrich-Heine-Universität, Düsseldorf**

Recruitment

- **Planned/Actual: Actual**
- **(Anticipated or Actual) Date of First Enrollment: 2017/01/01**
- **Target Sample Size: 320**
- **Monocenter/Multicenter trial: Multicenter trial**
- **National/International: National**

Inclusion Criteria

- **Gender: Both, male and female**



Gender: **Both, male and female**

■ Minimum Age: **18 Years**

■ Maximum Age: **65 Years**

Additional Inclusion Criteria

**Patientgroup 1:
actually treatment in hospital
age 18-65 years
diagnosis (ICD10): F32 and F33**

**Patientgroup 2:
actually treatment in hospital
age 18-65 years
diagnosis (ICD10): F20 and F25**

**medical staff group 1:
physicians in psychiatric hospital**

**medical staff group 2:
nurses in psychaitric hospital**

Exclusion criteria

**enforced stay in hospital
limited contractual capability**

Addresses

■ **Primary Sponsor**

**LVR-Klinik Köln
Wilhelm-Griesinger-Str. 23
51109 Köln
Germany**

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URL: [---]*

■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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Status

■ Recruitment Status: **Recruiting complete, follow-up continuing**

■ Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

DRKS-ID: **DRKS00009619**

Date of Registration in DRKS: **2015/11/05**

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* *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.*