Trial Description

Title

Effectiveness of Pulmonary Rehabilitation in Patients with asthma ("EPRA study") - A prospective randomized intervention study (waiting group design)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

While the effectiveness of pulmonary rehabilitation in COPD is secured with the highest level of evidence, the available data regarding the rehabilitation of asthma are sparse. In fact, so far neither in the national nor in the international literature there are only very randomized controlled trials (RCTs) concerning the rehabilitation of asthma. This is of particular relevance because asthma is the most common indication for pulmonary rehabilitation in Germany.

The RCT (waiting group design) should clarify whether pulmonary rehabilitation in asthma provides relevant short and longterm improvements over the usual medical care (without rehabilitation).

The primary outcome parameter is the degree of asthma control (measured immediately after and 3 months after rehabilitation).

Secondary outcome parameters are the health-related quality of life, the submaximal physical performance, and the psychological burden of anxiety and depression, self-management skills, the number of emergency treatments, the number of doctor visits for asthma, the number of necessary cortisone treatments and / or antibiotic therapies for asthma exacerbations and the number of disability and hospital days.

To our knowledge, the proposed study is the first randomized controlled trial to examine the effectiveness of an inpatient rehabilitation program under the conditions in Germany compared to a control group ("routine care").

Brief Summary in Scientific Language

A RCT (waiting group design) should clarify whether pulmonary rehabilitation provides in patients with asthma short and medium term clinically relevant improvements over the usual outpatient medical care (without rehabilitation). The study also aims to observe in a longitudinal design, the course of relevant outcomes 12 months after the rehabilitation. Additionally health-economic characteristics will be investigated.
Primary outcome is the degree of asthma control (measured immediately before and after, and 3 months after rehabilitation).

Secondary outcome parameters are the health-related quality of life, symptom dyspnea, exercise capacity, anxiety and depression, self-management skills and the use of medical services and their costs.

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00007740**
- Date of Registration in DRKS: **2015/05/15**
- 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.: **15017 , Ethik-Kommission der Bayerischen Landesärztekammer**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1169-6242**

Health condition or Problem studied

- ICD10: **J45 - Asthma**

Interventions/Observational Groups

- Arm 1: **Prospective randomized intervention study with waiting group design. The intervention group undergoes a 3-week multimodal inpatient pulmonary rehabilitation 4 weeks after rehab authorization and consent.**
- Arm 2: **The control group undergoes the same rehabilitation, but 4 months after intervention group.**

Characteristics

- Study Type: **Interventional**

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- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary Outcome = asthma control. This is measured by the Asthma Control Test (ACT; Schatz et al., 2006) at T0, T1, T2 and T3 (parallel in the IG and CG = RCT). At the measurement times T4-T8 the results of the two groups will be pooled and analyzed the sense of an observational study (1 year follow-up).

IG: T0 = baseline = rehab permission (1 month before starting with rehab), T1 = Beginning of rehabilitation, T2 = End of rehabilitation (duration 3 weeks), T3, T4, T5, T6 = 3, 6, 9 and 12 months after discharge from rehab.
GC (passes the same rehab, but starts 4 months later). T0 = baseline, T1 = 4 months prior to rehabilitation, T2 = 3 months prior to rehabilitation, T3 = start of rehabilitation (duration 3 weeks), T4 = end of rehabilitation; T5-T8 = 3, 6, 9 and 12 months after the end of rehabilitation.

Secondary Outcome

Health-related quality of life (SGRQ, AQLQ, EQ-5D-5L), symptoms: dyspnea, cough, sputum, pain (numeric rating scales), GROC-scale, physical fitness (6MWT), psychological distress by anxiety and depression (PHQ-D, GAD7, IPQR , BFI, Nijmegen questionnaire), self-management skills (HeiQ, MARS-D, BMQ), smoking (self developed questionnaire), utilization and costs of health services (FIM Lu, WAI, SPE), number of cortisone courses and / or antibiotic therapies (self developed questionnaire). Secondary endpoints are measured at T0 - T8.

Abbreviations:
Asthma Control Test (ACT)
Saint George's Respiratory Questionnaire (SGRQ)
Asthma Quality of Life Questionnaire (AQLQ)
Health questionnaire EQ-5D-5L
GROC-scale (global rating of change scale)
Patient Health Questionnaire (PHQ) []
Generalized Anxiety Disorder Questionnaire (GAD 7)
Brief Fatigue Inventory (BFI)
SPE-scale
Work Ability Index - questionnaire (WAI) Item 1 and 4

Health Education Impact Questionnaire (HeiQ) Item 1 and 3
Revised Illness Perception Questionnaire (IPQ-R)
NQ = Nijmegen Questionnaire
FIM Lu, modification of FIMA
Brief Medication Questionnaire (BMQ)
Medication Adherence Report Scale (MARS)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinik Bad Reichenhall der DRV Bayern Süd, Bad Reichenhall**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/06/15**
- Target Sample Size: **503**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **95 Years**

Additional Inclusion Criteria

1. All rehabilitation patients with leading diagnosis Asthma (= rehabilitation diagnosis)
2nd and lack of asthma control (ACT ≤ 19 points)
3rd and Written informed consent

Exclusion criteria

1. Patients with a lack of language skills and / or
2. lacking cognitive ability and / or
3. severe comorbid diseases that overlay the results of the outcome parameters relevant and clinically leading (e. g. tumors, severe cardiac, orthopedic and psychological comorbidities)

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Addresses

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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 complete**
- Study Closing (LPLV): **2019/02/28**

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.*