Trial Description

Title

Avoidance of treatment failures during inhalation therapie: medical instruction versus eductation by a video

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of the current study is to investigate if a video to explain the correct inhalation of different devices is as effective compared to an explanation by a medical doctor concerning mistakes in handling the medication.

Brief Summary in Scientific Language

Patients with evidence of treatment failure in inhalation device wer identified. Patienst receive in a randomizied order either a medical instruction or education by a video. After 24h the treatment is reanalyzied and both interventions will be compared.

Organizational Data

- DRKS-ID: **DRKS00004320**
- Date of Registration in DRKS: **2012/09/12**
- 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.: **2012031 , Ethikkommission der Ärztekammer Nordrhein**

Secondary IDs

Health condition or Problem studied

- ICD10: **J44.8 - Other specified chronic obstructive pulmonary disease**

Interventions/Observational Groups

- Arm 1: **education video about inhalation therapy**
- Arm 2: **medical instruction about inhalation therapy**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Improvement in handling errors of inhalation therapie measured by a questionnaire. It is hypothesized that the education viedo is as effective compared to medical instruction avoidung handling errors after 24h.

Secondary Outcome

In line to primary outcome a subanalysis will be performed regarding two differnt devices for inhaltaion: metered dose inhaler and dry powder inhaler.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Lungenklinik Merheim, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/12/05**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

COPD-Patients on MDI (metered dose inhaler) or DPI (dry powder inhaler), who are admitted to the Cologne-Merheim Hospital, Kliniken der Stadt Köln gGmbH.

Exclusion criteria

Patients showing neurologic, congnitive or orthopedic problems leading to disfficulties in theh correct use of independent inhalation practise. Furthermor patients with no relevant failures of inhalation therapy (index < 2 points).

Addresses

- **Primary Sponsor**

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- **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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■ **Private sponsorship (foundations, study societies, etc.)**

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Private sponsorship (foundations, study societies, etc.)

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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/06/18**

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.*