Trial Description

Title

Analysis of routine data of therapy with intravenous opioid PCA for the relief of dyspnea in palliative care patients

Trial Acronym

URL of the trial

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Brief Summary in Lay Language

A therapy with a PCA (Patient Controlled Analgesia) is a patient-controlled pain-therapy using a pain pump. Such therapy for example is used in the treatment of chronic pain in cancer patients. In the treatment of dyspnea strong painkillers (opioids) are applied successfully for many years. In our experience, also palliative care patients under treatment of breathlessness can benefit of a patient-controlled therapy. For this theme no studies exist so far. In the context of therapy with a PCA pump, we want to analyze routinely collected data for further investigation of this kind of therapy. How satisfied are the patients with this treatment, which application rate of opiods is used by the patients, how often occur side effects?

Brief Summary in Scientific Language

The aim of this study is to check the feasibility, effectiveness and acceptability of patient-controlled opioid-therapy in patients with refractory dyspnea.

Organizational Data

- DRKS-ID: **DRKS00004232**
- Date of Registration in DRKS: **2012/07/17**
- 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.: **Studien-Nr. 3865 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1132-6335**

Health condition or Problem studied

- ICD10: **R06.0 - Dyspnoea**

Interventions/Observational Groups

- Arm 1: **Palliative care patients with dyspnoea receiving opioid-PCA therapy, assessment of the severity of dyspnea with a numeric rating scale from 0 to 10 (NRS 0 = no dyspnea, NRS 10 = maximal imaginable dyspnea), questionnaire on patient satisfaction; documentation of physiological parameters, of side effects and PCA data at specified points in time.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

Severity of dyspnea under opioid PCA therapy, on a numeric rating scale from 0 to 10 (NRS 0 = no breathlessness, NRS 10 = maximal imaginable breathlessness) severity is measured before the start of PCA therapy, 5 minutes, 15 minutes, 60-120 minutes, 1 day after initiation of therapy and at each subsequent day of therapy

Secondary Outcome

Changes in physiological parameters measured as respiratory rate, oxygen saturation and Palliative Performance Scale (PPS) before the start of PCA therapy, 5 minutes, 15 minutes, 60-120 minutes, 1 day after initiation of therapy and at each subsequent day of therapy; the measuring of satisfaction and acceptance of the therapy using a 6-question questionnaire, 24 and 72 hours after initiation of therapy; description of adverse reactions under PCA opioid therapy before the start of PCA therapy, 5 minutes, 15 minutes, 60-120 minutes, 1 day after initiation of therapy and at each subsequent day of therapy; application profile (opioids and their doses, PCA parameters: bolus dose, basal rate, locking time, number and

size of boluses given by physicians, number of required and administered boluses by the patient, total dose) before the start of PCA therapy, 5 minutes, 15 minutes, 60-120 minutes, 1 day after initiation of therapy and at each subsequent day of therapy

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Interdisziplinäres Zentrum für Palliativmedizin, Düsseldorf**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/08/14**
- Target Sample Size: **18**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Dyspnea >/= NRS 3; inpatients of the University Hospital Dusseldorf, who are treated by the Interdisciplinary Center for Palliative Medicine; indication for PCA therapy in the context of standard treatment of dyspnea; cognitive, physical and verbal skills, that allow the correct handling of a PCA pump

Exclusion criteria

cognitive, physical and/or linguistic limitation that does not allow the correct handling of an PCA pump; Minimal-Mental State Examination (MMSE) <24 (of 30 max.); allergy, known intolerance or contraindications to morphine and hydromorphone; pregnancy; taking monoamine oxidase inhibitors (MAOI) in the last 2 weeks

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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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/12/14**

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.*