Trial Description

Title

Analgetic Treatment in HEMS

Trial Acronym

Pain is not in the Air

URL of the trial

[---]*

Brief Summary in Lay Language

One of the most important goals of prehospital emergency medicine is a fast and sufficient pain treatment. Nevertheless not alle patients receive a sufficient analgesia. Up to 12-54% of all patients suffer from insufficient pain treatment. This means, that sufficient prehospital analgesia must get into our focus. Up to now, there exist only monocentric studies regarding this topic. The main goal of the study is to analyze the status quo of prehospital pain therapy in helicopter emergency missions (HEMS) all over Germany.
Different causes of pain, like trauma or non-traumatic reasons (e.g. heart attack, stroke, back pain etc.) should be evaluated.
A special interest is what type of analgesia is in these different situations most effective.

Brief Summary in Scientific Language

One of the most important goals of prehospital emergency medicine is a fast and sufficient pain treatment. Nevertheless not alle patients receive a sufficient analgesia. Up to 12-54% of all patients suffer from insufficient pain treatment. This means, that sufficient prehospital analgesia must get into our focus.

Up to now, only monocentric studies exist on this topic.
The main goal of our study is to analyze the status quo of prehospital pain therapy in physician assisted helicopter emergency missions (p-HEMS) all over Germany.
Different causes of pain, like traumatic or non-traumatic reasons (e.g. heart attack, stroke, back pain etc.) should be evaluated.

A special interest is which type of analgesic treatment is in different situations most effective.

This study is a secondary data analysis (1.1.2005 - 31.12.2017), including all patients treated by p-HEMS (physician assisted helicopter emergency medical service) crew of the German Air-Ambulance (ADAC Luftrettung GmbH) who met the following inclusion criteria:
- primary mission (scene to hospital)
- Numeric rating scale (NRS) >= 3 at the scene
- National Advisory Committee for Aeronautics (NACA) score < =VI.

The study has received a positive vote from the Ethics Commission of the University of Ulm, Germany (request no. 003/16).

Subgroup analysis

1. patient sex
2. patient age
3. date of mission
4. coded and classified diagnosis (Trauma, non trauma, cardiovascular stability etc.)

Primary and secondary endpoint:

- sufficient pain therapy at handover to hospital (primar endpoint)
- vital signs at handover to hospital
- Glasgow Coma Scale at handover to hospital
- type of prehospital analgesic treatment (opioid, non opioid, non medical pain treatment etc.)

Organizational Data

- DRKS-ID: **DRKS00015035**
- Date of Registration in DRKS: **2018/07/16**
- 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.: **03/16 , Ethik-Kommission der Universität Ulm**

Secondary IDs

Health condition or Problem studied

- ICD10: **R52 - Pain, not elsewhere classified**
- ICD10: **T07 - Unspecified multiple injuries**
- ICD10: **T14 - Injury of unspecified body region**
- ICD10: **I64 - Stroke, not specified as haemorrhage or infarction**
- ICD10: **I24 - Other acute ischaemic heart diseases**
- ICD10: **M54 - Dorsalgia**
- ICD10: **T95 - Sequelae of burns, corrosions and frostbite**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>This study is a secondary data analysis (1.1.2005 - 31.12.2017), including all patients treated by p-HEMS (physician assisted helicopter emergency medical service) crew of the German Air-Ambulance (ADAC Luftrettung GmbH) who met the following inclusion criteria:
  - primary mission (scene to hospital)
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Characteristics

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

Primary Outcome

- sufficient pain therapy at handover to hospital (numerical pain scale <=3 at handover at hospital or pain reduction of more than 3 NRS points)

Secondary Outcome

- vital signs at handover to hospital
- Glasgow Coma Scale at handover to hospital
- type of prehospital analgesic treatment (opioid, non opioid, non medical pain treatment etc.)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **alle vom ADAC Luftrettungsdienst angeflogenen Standorte, Deutschland**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/08/01**
- Target Sample Size: **100000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Pain on scene (first contact) >= 3 NRS points (numeric rating scale) and a NACA score of <= 6 points

Exclusion criteria

secondary mission (transfer from one hospital to another)

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

  Bundeswehrkrankenhaus Ulm Klinik für Anästhesiologie und Intensivmedizin
  Mr. PD Dr. med. Martin Kulla

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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 planned**
- 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.*