

Trial Description

Title

Feasibility study: Evaluation of methods for continuous pain assessment based on contactless recording of vital and activity parameters

Trial Acronym

Optic Pain Score

URL of the trial

[---]*

Brief Summary in Lay Language

Invasive procedures can be associated with pain. It is informative to monitor pain perception during interventions. Usually pain assessment is done by nurses or doctors to guide pain therapy. To assess the level of pain continuously and contactless by the use of a camera-based algorithm and in conjunction with vital parameters would be another option to ease pain management. The use of such a video-System should be tested within this feasibility study. The data are analysed with regard to patterns of mimics in conjunction with vital signs and opposed the pain levels expressed by patients.

Brief Summary in Scientific Language

Continuous and contactless technologies can ease pain monitoring and therefore improve pain therapy in the future. This requires the development of algorithms to evaluate patterns of mimics in conjunction with vital Parameters in a camera based System, which uses photoplethysmography. Patiens undergoing selected EP-studies should be monitored with the camerasystem. It should be evaluated to what extent it is feasible to assess pain levels during the procedure with the camera based techonology. The Treatment is not affected by the camera-monitoring.

Organizational Data

- DRKS-ID: **DRKS00013579**
- Date of Registration in DRKS: **2017/12/12**
- 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.: **083/17-ek , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **I48.1 - Persistent atrial fibrillation**
- ICD10: **R52.0 - Acute pain**

Interventions/Observational Groups

- Arm 1: **Patients undergoing selected routine EP-studies with only mild or no sedation are evaluated. Vital Signs (heart frequency, blood pressure, oxygen saturation) and pain level mentioned by the patient (NRS (0-10) every 5 min are collected. Additionnally videosignals of the face are recorded throughout the intervention. Patients serve as their own controls.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- 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

Patterns of Mimics and vital Parameters derived with the help of the camera. Data are analysed and evaluated to what extent they can be used to assess pain Levels and develop a reliable pain score.

Secondary Outcome

n/a



Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Herzzentrum Leipzig, Abteilung für Rhythmologie, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/12/19**
- Target Sample Size: **30**
- 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

Patients undergoing selected routine EP-studies with only mild or no sedation are evaluated.

Exclusion criteria

patients not fulfilling the above mentioned criteria as well as patients with cognitive impairments and severe presbyakusis.

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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URL: [---]*

Status

■ Recruitment Status: **Recruiting ongoing**

■ 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.