Trial Description

Title

Transcutaneous electrical nerve stimulation (TENS) for advanced cancer pain patients - A randomized, double-blind, placebo-controlled cross-over pilot study

Trial Acronym

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URL of the trial

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Brief Summary in Lay Language

Sometimes cancer patients suffer from pain despite medication, e.g. chronic pain or incident pain. A device for transcutaneous electrical nerve stimulation (TENS) can be used as complementary treatment in such cases.
The study aims at evaluating the efficacy and safety of TENS in advanced cancer pain patients.
Moreover, the efficacy of TENS will be evaluated in certain groups of patients (subgroups).

Brief Summary in Scientific Language

Pain is the most common symptom (ca. 80% of patients) on German Palliative Care units (Radbruch 2003) and thus, pain control plays a central role in palliative care (Worldwide Palliative Care Alliance 2014).
Transcutaneous electrical nerve stimulation (TENS) is a complementary treatment option for patients who experience suboptimal pain control. However, the evidence for the efficacy of TENS in cancer patients is not unambiguous (Hurlow 2012, Bennett 2011, Bennett 2010).
The present study is a double blind, placebo-controlled cross-over trial with a short-term follow-up.
The primary aim of this study is to evaluate the efficacy and safety of TENS for cancer pain reduction in advanced cancer patients.
The secondary aim is the explorative identification of subgroups that benefit or do not benefit from TENS.
The explorative subgroup analysis will, amongst others, include:
- Baseline pain intensity: 11-point Numerical Rating Scale (NRS) ≥ 5 vs. NRS 3-4
- Type of pain: somatic vs. visceral vs. neuropathic

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: **DRKS00007990**
- Date of Registration in DRKS: **2016/01/15**
- Date of Registration in Partner Registry or other Primary Registry: **2016/01/08**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **143/15 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1177-9586**
- Primary Registry-ID: **NCT02655289 (ClinicalTrials.gov)**

Health condition or Problem studied

- Free text: **Cancer pain patients receiving palliative care**

Interventions/Observational Groups

- Arm 1: **Modulated TENS:**
  - Frequency: 100 Hz
  - Intensity: individual; TENS should be clearly perceptible but not painful; impulse width is coupled with intensity
  - Mode: intensity modulation (40% decrease every 0.5 seconds)
  - TENS device: ARTROSTIM® SELECT
  - Channels: 2
  - Electrodes: 4 (5x5cm), placed on site of pain (a little more proximal if allodynia is present)

- Arm 2: **Placebo TENS:**
  - Frequency: 100 Hz (conventional for High TENS; Placebo is achieved by reduction of intensity, see below)
  - Intensity: The device is on and will be up-regulated together until the first sensation is perceptible. Then the activated device will be down-regulated minimally (no sensation perceptible) and this configuration will be retained.
  - Mode: continuous
  - TENS device: ARTROSTIM® SELECT
  - Channels: 2
  - Electrodes: 4 (5x5cm), placed on site of pain (a little proximal if allodynia is present)

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, assessor**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- Change of mean pain intensity last 24 hours; Before and after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point Numerical Rating Scale (NRS): 0-10; 0=no pain; 10=pain as bad as you can imagine

Secondary Outcome

- Change of worst pain intensity last 24 hours;Before and after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS
- Change of least pain intensity last 24 hours; Before and after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS
- Change of pain perception during TENS application on NRS; After the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS 0-100%; 0% = no alleviation, 100% = complete alleviation
- Change of pain perception during TENS application on VRS; After the 24-hour-interventions and after the follow-up: at an average of one week; 7-point verbal rating scale (VRS): 7-point verbal rating scale (VRS): 1= "very considerable deterioration", 2= "considerable deterioration", 3= "slight deterioration", 4= "unchanged", 5="slight improvement", 6= "considerable improvement", 7= "very considerable improvement"
- Number and percent of responders; After the 24-hour-interventions and after the follow-up: at an average of one week; Number and percent, responder: Patients with at least "slight improvement" on VRS (see outcome before) during TENS application
- Quality of life last 24 hours; Before and after the 24-hour-interventions and after the follow-up: at an average of one week; Question 30 from EORTC QLQ-C30
- General Activity; Before and after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS
- Mood; Before and after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS
- Walking ability; Before and after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS
- Normal Work (includes both work outside the home and housework); Before and

after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS
- Relations with other people; Before and after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS
- Sleep; Before and after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS
- Enjoyment of life; Before and after the 24-hour-interventions and after the follow-up: at an average of one week; 11-point NRS

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Palliative Care Unit, Palliative Care consultant service, acute pain consultant service, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/02/15**
- 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: **99 Years**

Additional Inclusion Criteria

- Patients with cancer pain (caused by tumor or therapy; or associated with tumor) ≥ 3 on an 11-point NRS the last 24 hours
- Age: ≥ 18 years
- Patients receive at least 24 hours palliative care: on palliative care ward, palliative care consultant service or acute pain consultant service

Exclusion criteria

- Verbal or cognitive inability to use TENS or to answer the questionnaire
- High probability of dying within the next week

- Pain that is not directly or indirectly related to tumor

Contraindications: Jones (2009) & Disselhoff (2012)
- electronic implants like pacemakers
- Metal implant on electrode site
- Arrhythmia
- Pregnancy
- Epilepsy
- Dermatological conditions or frail skin on electrode site
- Anamnestically known distinct allergy regarding electrodes

Drop-out criteria after inclusion:
- Patients that decide to stop TENS treatment (at any time or any reason).
- Further treatment is not indicated due a rapid deterioration of the patients' clinical status according to the treating physician.

Addresses

- **Primary Sponsor**

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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): **2018/03/16**

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.*