Trial Description

Title

The preventive effect of Sensorimotor- and vibration exercises on the onset of Oxaliplatin- or vinka alcaloid induced peripheral neuropathies

Trial Acronym

STOP

URL of the trial

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Brief Summary in Lay Language

Patients receiving chemotherapy containing oxaliplatin or a vinc alcaloid, develop a chemotherapie-induced peripheral neuropathy (CIPN) to 70-90%. Previous studies have shown that specific exercise interventions have the potential to influence the onset and progression of peripheral neuropathies. We would therefore like to conduct a randomised, controlled, prospective study to evaluate the effects of sensorimotor- or vibration exercises on the onset of CIPN.

Brief Summary in Scientific Language

The effects of sensorimotor- or vibration exercises on oxaliplatin- or vinc alkaloid-induced peripheral neuropathies.

Organizational Data

- DRKS-ID: **DRKS00006088**
- Date of Registration in DRKS: **2014/05/07**
- 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.: **21/2014 , Ethikkommission der Deutschen Sporthochschule Köln, Institut für Pädagogik und Philosophie**

Secondary IDs

Health condition or Problem studied

- ICD10: **C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue**
- ICD10: **C50-C50 - Malignant neoplasm of breast**
- ICD10: **C15-C26 - Malignant neoplasms of digestive organs**
- ICD10: **C81-C96 - Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue**

Interventions/Observational Groups

- Arm 1: **Sensorimotor training: the exercises are progressively difficult, starting bipedal on a static surface to monopedal on an instable surface. Four exercises will be performed per training session, each consisting of 3 repetitions with a duration of 20sec. and a rest of 40sec.. Between each exercise, a rest of 3min will be given in order to avoid neuronal fatigue. The Exercises will e perfomed barefoot or in socks, knees slightly bent (~30°) with the aim to maintain balance without holding on to sth or having to set the other foot down in the monopedal stance. The exercises will be performed at least twice a week for the entire duration of medical therapy (~2-3months).**
- Arm 2: **Patients will train on side-alternating vibration platform (Galileo Med M - Novotec). This training will also be conducted progressively. Patients will perfom 4 Exercises with a duration of 30sec.-2min at a frequency of 18-30Hz and an amplitude of 2-4mm. A rest of at least 1min, better 5min, must be kept between each exercise to avoid neuronal fatigue.**
The exercises will be performed at least twice a week for the entire duration of medical therapy (~2-3months).
- Arm 3: **Patients in the control group will be given the standard medical care according to the current standards, once a neuropathy is diagnosed. This can involve medication such as Gabapentin or Pregabalin as well as physiotherapie but excluded sensorimotor- or vibration exercises.**

Characteristics

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

Primary Outcome

Onset and time-point of chemotherapy-induced peripheral neuropathy (Nerve

conduction velocity (<40) and amplitude (<5) via neuroeletrography, Achilles- and patellar reflexes with a reflex hammer, peripheral deep sensitivity with a tuning fork, proprioception- manually)
Baseline assessment will be performed prior to therapy (T0), once neuropathy related symptoms are reported (T1) (which will also be checked every 6 weeks via a short neurological assessment -solely excluding the neuroelectrography) and after completion of therapy - after 2-3months (T2). In case therapy continues for more than 3 months, T2 will be performed as an intermediate measuring point and a further will be necessary after completion of therapy (T3).

Secondary Outcome

subjective assessment of neuropathy related symptoms (FACT-gog-ntx)
Quality of life (EORTC-QLQ-C-30)
Neuropathy related pain (PAIN-DETECT)
level of activity (GPAQ)
Baseline assessment will be performed prior to therapy (T0), once neuropathy related symptoms are reported or identified (T1) and after completion of therapy - after 2-3months (T2). In case therapy continues for more than 3 months, T2 will be performed as an intermediate measuring point and a further will be necessary after completion of therapy (T3).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Onkologie und Hämatologie , Köln**
- Medical Center **Onkologie und Hämatologie, Eschweiler**
- Doctor's Practice **Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/05/08**
- Target Sample Size: **158**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Minimum Age: **18 Years**

Maximum Age: **75 Years**

Additional Inclusion Criteria

>18years old
indication for chemotherapy containing either Oxaliplatin or vinka alcaloid

Exclusion criteria

- PNP (NCV <40; amp <5) of other derivation (such as diabetes, HIV, alcohol)
- all conditions preventing the active particpation in physical activity
- contraindications for vibration exercises (osteolyses, osteosyntheses, hip-TEP, a fracture of the lower extremities in the past 2 years, acute thrombosis, foot ulcers, fresh wounds and scar tissue)
- planed operation
- unwillingness to sign the informed consent and data protection
- uncontrolled cerebral seizures
- CNS metastases
- physical or psychological condition that does not allow the participation in a study or a legal signature for the informed consent statement, according to the principal investigator

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 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.*