PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

FLY-Pilot
Influence of chemotherapy, age an a single bout of endurance exercise on epigenetic modifications in tumor competetive immune cells after Non-Hodgkin Lymphoma

Trial Acronym

FLY

URL of the trial

[---]*

Brief Summary in Lay Language

In the present study the influence of two different chemotherapy protocols, age and a single bout of exercise on molecular changes in immune cells will be investigated. Further we will investigate if the named factors have an impact on EEG patterns and cognitive abilities.

Brief Summary in Scientific Language

In the present study the influence of two different chemotherapy protocols (R-CHOP, R-Bendamustine), age and a single bout of exercise on epigenetic changes (Acetylation H3K9, H4K5) in tumorcompetetive cells (NK-cells and CD8+ T-Lymphocytes) will be investigated. Further we will investigate if the named factors have an impact on EEG patterns and cognitive abilities (Attention).

Organizational Data

- DRKS-ID: **DRKS00004743**
- Date of Registration in DRKS: **2013/02/22**
- 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.: **40/2011 , Ethikkommission der Deutschen Sporthochschule Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **C82 - Follicular lymphoma**
- ICD10: **C83 - Non-follicular lymphoma**
- Free text: **Healthy adults**

Interventions/Observational Groups

- Arm 1: **Patients, treated because of indolent NHL. 5 out of the 10 patients exercise 30 minutes on a bycyleergometer after randomization. After the work-out cognition tests will be performed. Blood samples are taken before the intervention and after the cognition tests. EEG Data will be collected during the whole investigation (Rest, Exercise, Cognition).**
- Arm 2: **Patients treated because of agressive NHL. 5 out of the 10 patients exercise 30 minutes on a bycyleergometer after randomization. After the work-out cognition tests will be performed. Blood samples are taken before the intervention and after the cognition tests. EEG Data will be collected during the whole investigation (Rest, Exercise, Cognition).**
- Arm 3: **Young, healthy controls. 5 out of the 10 patients exercise 30 minutes on a bycyleergometer after randomization. After the work-out cognition tests will be performed. Blood samples are taken before the intervention and after the cognition tests. EEG Data will be collected during the whole investigation (Rest, Exercise, Cognition).**
- Arm 4: **Older, healthy controls. 5 out of the 10 patients exercise 30 minutes on a bycyleergometer after randomization. After the work-out cognition tests will be performed. Blood samples are taken before the intervention and after the cognition tests. EEG Data will be collected during the whole investigation (Rest, Exercise, Cognition).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **No treatment**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

H3K9 und H4K5 Acetylation in NK-cells and CD8+ T-Lymphocytes

Measure Timepoinzs: T1 Pre (before endurance session and cognition testing), T2 Post (after endurance and cognition testing)

Methods: PBMC Isolation, MACS Sorting, DAB Staining, ImageJ Valuation

Secondary Outcome

Cytokines (TNF alpha, MIF) > T1 and T2

Fatigue > pre Intervention (T1) > Questionaires (BFI, MFI-20, EORTC QLQ-C30)

EEG (IAF) > during rest, endurance exercise and cognition tests

Executive function > Wiener Testsystem

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/03/20**
- Target Sample Size: **40**
- 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

The end of the first line Chemotherapy should not be dated back longer than 24 weeks in both patient groups

Written consent

Exclusion criteria

- **Hb< 8 g/dl**
- **Thrombocytopenia < 10 000/µl**
- **Hypothyreosis**
- **NYHA > III**
- **Symptomatic Coronary heart disease**
- **COPD**
- **Respiratory Globa linsufficiens**
- **Medical treatment of Fatigue**
- **cerebral cramping**
- **fatigable drug intake**
- **medical or psychological state that prevents patient to participate**

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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URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/10/31**

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.*