Trial Description

Title

Cognitive function in patients with gynecological tumors

Trial Acronym

COGNIFiT

URL of the trial

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Brief Summary in Lay Language

Cancer patients often suffer from tiredness and listlessness, which can strongly influence the general quality of life. This syndrome, also called fatigue, can cause limitations in physical, emotional and mental areas of daily life. Physical activity and sleep patterns can also be affected by medical treatment.
In addition, during and after medical cancer treatments, patients repeatedly report a loss of brain performance (e.g. concentration, memory). The scientific data on this phenomenon is contradictory and there are differences between the experienced and the measurable losses.
On this basis, the COGNIFit study is intended to gain more comprehensive knowledge to better understand the influence of various therapies and other influencing variables on cognitive functions (brain performance) and to create a basis for implementing these findings in everyday medical practice in the long term.
Approximately 200 cancer patients will participate in this study over a period of three years.

Brief Summary in Scientific Language

Up to 80% of all cancer patients complain about cognitive impairments during medical treatment, known under the term "chemobrain". About 35% of all patients still describe cognitive deficits even years after the end of treatment, mainly manifesting in memory and concentration deficits, which do not only make returning to work difficult but ultimately reduce the quality of life of those affected. Despite the great relevance of the topic, little is known about the exact causes and mechanisms so far. Although studies have shown structural changes of the brain after various types of medical treatment, there is a blatant discrepancy between subjectively and objectively measured cognitive impairments. It is also unclear whether cognitive impairments are exclusively caused by medical treatment or whether it is also influenced by psycho-social factors (anxiety, depression, fatigue, sleep disorders, physical activity). Due to the use of both heterogeneous objective and subjective cognitive measures as well as an inadequate recording of influencing factors and biological mediators the informative value of the studies conducted so far is limited. Against this background, the COGNIFiT study will include an objective measurement of cognitive functions as recommended by the International Cancer and Cognition Task Force (ICCTF) in combination with an established questionnaire on subjectively perceived cognitive performance. Furthermore, potential biological

and psycho-social influencing factors before and after drug therapy (especially chemo- and hormone therapy) in patients with different gynecological tumor types will be investigated. In addition, a subgroup of patients with immunotherapy will be examined for the first time. Over a period of 36 months, 200 patients at the NCT will undergo this assessment, which can be easily integrated into the medical routine. The results of the study will not only provide information on the severity of cognitive impairments but also on their causes and mechanisms. They will form the basis for effective preventive and supportive therapy measures at the NCT and may also have an impact on patients' fear of cognitive deficits.

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: **DRKS00015757**
- Date of Registration in DRKS: **2018/10/29**
- 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.: **S-489/2018 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **C50 - Malignant neoplasm of breast**
- ICD10: **C51-C58 - Malignant neoplasms of female genital organs**

Interventions/Observational Groups

- Arm 1: **In order to investigate the influence of different medical treatments on cognitive abilities longitudinally, patients with breast cancer or gynecological tumors are cognitively tested at 3 measurement points (before the start of first-line therapy, after completion of first-line therapy (T2) and one year after T2) using the HVLT-R (Hopkins Verbal Learning Test-Revised), TMT A/B (Trail Making Test A and B) and the Pattern Separation Task. In addition, subjective**

parameters and data on mediator variables (movement questionnaire, FACT-cog, CES-D, EORTC-FA12, VAS, PSQI, return to work) are recorded at all measurement times.

- Arm 2: **In addition to the patients, data will be collected in a healthy control group (n=30) in order to classify the patient data according to their clinical relevance.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Supportive care**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The influence of different first-line medical therapies on verbal memory performance of gynecological cancer patients. Verbal memory performance is enhanced by the Hopkins Verbal Learning Test - Revised (HVLT-R), whereby the variable "Total Recall" is defined as the primary target parameter.
The endpoints mentioned will be recorded at three measurement times:
- Before starting the first-line therapy (T1)
- 7-14 days after completion of first-line therapy, with a maximum of 6 months after completing the first-line therapy (T2)
- One year after T2 (T3)

Secondary Outcome

- Influence of different first-line medical therapies on other objectively measured cognitive domains
o attention: Trail Making Test (TMT) A
o cognitive flexibility: TMT B
o visual differentiation capability: Visual Pattern Separation Task
- Influence of first-line medical therapy on the subjective cognitive performance, measured using the FACTcog
- Influence of first-line medical therapy on systemic inflammatory status and the peripheral concentration of neurotrophic factors.

For the detection of peripheral inflammation markers and the concentration of neurotrophic factors, 9 ml of venous blood is taken from the study participants and archived as serum at -80 °C. The analyses are performed in the NCT (Nationales Centrum für Tumorerkrankungen) after completion of the last patient

examination using Enzyme-Linked ImmunoSorbent Assay (ELISA). Currently planned target parameters are Interleukin-6, Interleukin-1, Receptor antagonist, brain-derived neurotrophic factor, tryptophan, kynurenine, kynurenic acid and quinolinic acid.
The final selection of the parameters takes place before starting with the analysis on the basis of the current literature.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Nationales Centrum für Tumorerkrankungen, Heidelberg**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/11/12**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Inclusion criteria for patients
- Female
- Age ≥ 18 years
- Diagnosis of breast cancer or gynecological tumor
- Before the start of a first-line therapy from the following categories:
o Chemotherapy
o Radiotherapy
o Hormone therapy
o Immunotherapy

Inclusion criteria for healthy control group (n=30)
- Female
- Age ≥ 18 years
- native speaker

Exclusion criteria

Exclusion criteria for patients and healthy control group:
- Previous, known or treated tumor disease
- Known neurodegenerative diseases (e.g. MS, Alzheimer's, Huntington's)
- Known psychological diseases
- Known neurological damage (e.g. epilepsy, apoplexy)
- thyroid disorders
- Medication that has a proven effect on cognitive performance

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 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.*