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

Trial Description

Title

Reducing the subjective experience of side effects during chemotherapy through education about the Nocebo-effect in therapy-naive patients with gastrointestinal tumors - RENNO study

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

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Brief Summary in Scientific Language

This study investigates the role of information about the nocebo-effect on experiencing side effects. Secondly, this trial examines the effect of information about side effect-related experience, toxicity, intake of supportive medication, coping of side effects and patient compliance during chemotherapy. Patients are randomized to an experimental group (information about the nocebo-effect) or the control group (interview about quality of life) in this univariate design.

Organizational Data

- DRKS-ID: **DRKS00009501**
- Date of Registration in DRKS: **2018/03/27**
- 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.: **[---]* , Ethikkommission der Fakultät für Psychologie und Bewegungswissenschaft der Universität Hamburg**

Secondary IDs

Health condition or Problem studied

- Free text: **gastrointestinal tumors**

Interventions/Observational Groups

- Arm 1: **Experimental arm: Patients receive information about the nocebo-effect**
- Arm 2: **control arm: Patients receive information about quality of life (instead of information about the nocebo-effect)**

Characteristics

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

Primary Outcome

Primary outcome: Experiencing of side effects. We use an adapted version of the GASE (General assessment of side effects scale) containing the 4 main side effects after chemotherapy (nausea, vomiting, diarrhea, fatigue) and 3 more unspecified side effects (headache, dyspnea, skin rash) on a 10-level scale. The overall impact of side effects for the last 7 days is measured. The attribution of side effects on the medical product is determined. Follow up surveys take place on day 10 (T2) and 12 weeks (T3) after start of therapy. Questionnaires will be sent by mail.

Secondary Outcome

Toxicity: toxicity will be questioned by Common Toxicity Criteria Version 4 at baseline and prior every cycle of therapy. Coping of side effects will be interrogated by questionnaire (10-level scale) asking on managing side effects. Patient compliance while on chemotherapy will be determined by observation of behaviour and noted in in the electronical health record. The intention to complete therapy and the estimated probability to discontinue therapy will be recorded. Side effect-related expectations will be recorded with 8 items before and after information on nocebo or control intervention.

On a 10-level scale patients will be asked to determine the range of expectancy of the following side effects: nausea, diarrhea, fatigue, headache, dyspnea, skin rash.
Coping expectancy on side effects: on a 10-level scale patients will be asked to note how they expect to manage and control side effects. Patients are asked to state whether chemotherapy will help them and how far they believe to influence the course of disease themselves.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Onkologisch-Hämatologische Ambulanz, Hamburg**
- Doctor's Practice **Hamburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/01/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. newly diagnosed tumor of gastrointestinal tract
2. therapy-naive patient
3. planned chemotherapy with/without monoclonal antibody (except EGFR-inhibitors) neoadjuvant, adjuvant or palliative
4. ECOG < 2
5. 18 years or older
6. adequate knowledge of German language
7. signed informed consent

Exclusion criteria

1. prior chemotherapy
2. combination of EGFR inhibitor (Cetuximab or Panitumumab) or combination with inhibitor of tyrosinkinase domain of EGF-receptor (Erlotonib)
3. prior skin disease
4. anamnestic chronic pulmonary disease
5. dyspnea and skin disease before start of therapy
6. acute mental stress or illness that may affect quality of life (physician's opinion)

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 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.*