E-Health Portal for Individualized Treatment Monitoring and Patient Engagement in Oncology Research

NCT-Nummer:
NCT03132506

Studienbeginn:
Juni 2017

Letztes Update:
11.02.2020

Wirkstoff:
-

Geschlecht:
Frauen

Altersgruppe:
Erwachsene (18+)

Phase:
-

Sponsor:
University Women's Hospital Tübingen

Collaborator:
National Center for Tumor Diseases (NCT), University Hospital Heidelberg, Germany, Department of Gynecology and Obstetrics, University Hospital Heidelberg, Germany, Department of Gynecology and Obstetrics, University Hospital Erlangen, Germany,

Studien-Informationen

Detailed Description:

Paperbacked pPRO data from up to a total of 100 patients from the cohort of PRAEGNANT are planned to be included in the Pepper I PRO study. Additionally 200 patients will be recruited in the web based ePRO cohort. The study duration per patient is at least 8 weeks. In cases of stable disease the study duration can be extended to up to 6 months with monthly PRO assessments, according to the attached visit matrix, taking approximately 20 minutes per visit.

The documentation at baseline should be performed during clinical routine with trained study personnel followed by remote self-reporting to minimize the patient effort. Pepper I will be

conducted as sub-protocol of the PRAEGNANT trial.

Ein-/Ausschlusskriterien

Inclusion Criteria:

- Patients enrolled in PRAEGNANT

- Women aged ≥18 years

- Patients with the diagnosis metastasized breast cancer undergoing any form of systemic therapy

- Patients who are willing and able to sign the informed consent form

- Patients with therapy change

Exclusion Criteria:

- Patients who are not eligible for observation due to severe comorbidities or unavailability according to the treating physician

- Patients who are not able to handle a tablet computer or are unable to write

- Patients who are not able to understand the nature and extent of the trial and the procedures require

Studien-Rationale

Primary outcome:

1. QLQ-C30 questionnaire for baseline (Time Frame - 8 weeks):
Overall patient completion rate in the paperbacked questionnaire and the web-tool, respectively

Secondary outcome:

1. All other questionnaires for baseline and follow up time points. (Time Frame - Baseline, 8 weeks):
Overall patient completion rate in the paperbacked questionnaire and the web-tool, respectively,

2. Influence factors for the completion rates (Time Frame - 8 weeks):
age

3. Influence factors for the completion rates (Time Frame - 8 weeks):
line of treatment

4. Influence factors for the completion rates (Time Frame - 8 weeks):

treatment

5. Influence factors for the completion rates (Time Frame - 8 weeks):
technical skills

6. Influence factors for the completion rates (Time Frame - 8 weeks):
patient's satisfaction

7. Adverse events-1 (Time Frame - 8 weeks):
The date of clinical diagnosis of AE compared with the date of early AE onset

8. Adverse events-2 (Time Frame - 8 weeks):
Consistency of AE documentation ePRO and clinician based

9. Patient satisfaction (Time Frame - baseline, 4 weeks, 8 weeks):
at baseline, after 4 weeks and after 8 weeks

10. Health related quality of life (HRQL) assessements -1 (Time Frame - baseline, 4 weeks, 8 weeks):
EORTC QLQ C-30

11. Health related quality of life (HRQL) assessements -1 (Time Frame - baseline, 4 weeks, 8 weeks):
BR23

12. Health related quality of life (HRQL) assessements -1 (Time Frame - baseline, 4 weeks, 8 weeks):
NCCN distress thermometer,

13. Health related quality of life (HRQL) assessements -1 (Time Frame - baseline, 4 weeks, 8 weeks):
EQ-VAS

14. Health related quality of life (HRQL) assessements -1 (Time Frame - baseline, 4 weeks, 8 weeks):
PHQ-9

15. Health related quality of life (HRQL) assessements -2 (Time Frame - baseline, 8 weeks):
The HRQL assessements EQ-5D-5L measured at baseline and weekly (8 weeks)

16. Health related quality of life (HRQL) assessements -2 (Time Frame - baseline, 8 weeks):
The HRQL assessements PROCTCAE Endocrine measured at baseline and weekly (8 weeks)

17. Health related quality of life (HRQL) assessements -2 (Time Frame - baseline, 8 weeks):
The HRQL assessements PROCTCAE taxane measured at baseline and weekly (8 weeks)

Studien-Arme

- paper-based patient-reported-outcomes
- on web-based patient-reported-outcomes

Geprüfte Regime

- patient-reported-outcomes:
  Explorative pilot study combining collected data from the PRAEGNANT study on paper-based patient-reported-outcomes with additional collected data on web-based patient-reported-outcomes

Kontakt

Markus Wallwiener, MD
Kontakt:
Phone: 0049 6221 56-36956
E-Mail: markus.wallwiener@med.uni-heidelberg.de

Studienlocations (1 von 1)

Department for Women's Health
72076 Tübingen
(Baden-Württemberg)
Germany

Status: Rekrutierend

Quelle: ClinicalTrials.gov