GCIG SB-001/NSGO-CTU-PEACE/ANZGOG 1923/2020: Palliation in gynae-oncology: Patient´s Expectations and Assessment of Care

TPS5635

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Link to poster

BACKGROUND

Patients with advanced gynecological cancers who are approaching the end of life (EOL) have a high symptom burden and a low likelihood of response to further anti-cancer treatment. Despite this, 20-30% received chemotherapy in the last 30 days of life, with potentially detrimental effects on health and quality of life. Little is known about patients´ and careers' perceptions and preferences in this palliative situation. Eliciting patients' values and preferences for EOL care and shared decision-making are central elements of GCIG SB-001/NSGO-CTU-PEACE with the aim of improving patient-centered EOL care.

PRIMARY OBJECTIVES

To assess

- Feasibility of collecting data on patient satisfaction and shared decision making towards EOL.
- Patient compliance with completing ePROs

SECONDARY OBJECTIVES

To assess

- Carers compliance with completing ePROs Patients' satisfaction of care near the end of life
- Documentation of interventions near end of life

METHODS

Design:

- Prospective observational cohort study

Study population:

- Patients with gynecological cancer and with a predicted life expectancy of approximately 4 months.
- Must be able to complete patient-reported outcome measures independently
- Patients are encouraged to appoint a carer for participation (non-mandatory)

Procedures:

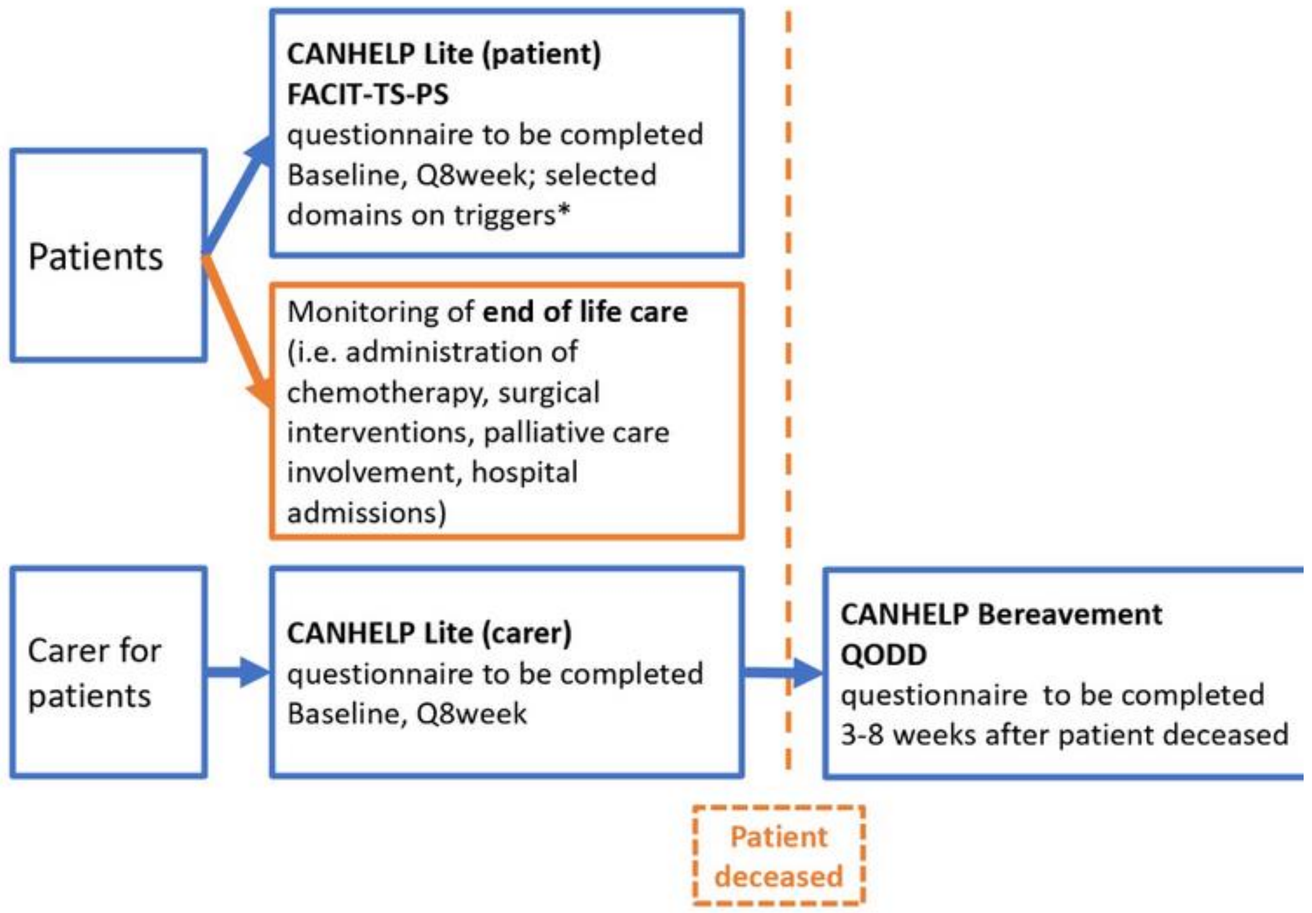
- Patient and carer satisfaction with care and shared decision-making and the importance of the different domains will be assessed with CANHELP-Lite individualized and FACIT at baseline and every 8th weeks.
- Carer's perception of the bereavement period and the quality of the patient's death will be assessed with the CANHELP Lite bereavement and the Quality of Death and Dying questionnaire.
- Additional patient satisfaction assessments will be triggered by ceasing anti-cancer therapy, changing in anti-cancer treatment, and at the discharge of unplanned hospital admissions

Power calculation:

- A sample size of 65 patients would have at least 80% power with 95% confidence to rule out a 60% completion rate in favor of the more interesting 75% rate. Assuming a 10% drop-out rate, PEACE will enroll 73 patients. Enrolment commenced in December 2022.

- ClinicalTrials.gov Identifier: NCT05142150

STUDY DESIGN



*Triggers: Change in anti-cancer treatment and at discharge of unplanned hospital admissions

STUDY INFORMATION

Sponsor: NSGO-CTU ,Copenhagen, Denmark
ENGOT-model: A
Study Chair: Kristina Lindemann
Study Statistician: Rene dePont Christensen, NSGO-CTU
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NSGO-CTU Nordic Society of Gynaecological Oncology - Clinical Trial Unit

ANZGOG

GCIG GYNECOLOGIC CANCER INTERGROUP