

Study Group - Ovarian Cancer

The core projects are a first prospective clinical trial on PARP inhibitor rechallenge in recurrent ovarian cancer (BZKF-OVAR 1) and a registry providing comprehensive realworld data (BAROC), which will be expanded to include imaging and biomaterials.

Speaker: PD Dr. Holger Bronger, Munich (TU)

Concept & Achievements

Questionnaire

BZKF-OVAR-1-01:

Reasons for the decision

PARPi

after

PARPi?

PARPi rechallenge

of the disease and the final decision on

(patient and physician)

Project 1:

BZKF-OVAR 1: PARP inhibitor rechallenge in recurrent ovarian cancer

- Prospective clinical trial to provide real-world data on a controversial, yet urgent clinical question
- Funding approved by the BZKF
- Study protocol completed
- Biomarker protocols harmonized
- Data protection issues cleared
- Ethics application granted
- eCRF design completed eCRF programming ongoing
- Next step: ,first patient in'

BZKF-OVAR 1:

Patient population (n>100)

Enrollment & key eligibility

Recurrent high-grade, non-

Successful platinum-based

chemotherapy for recurrent

Study design

Project 2: Treatment strategies for (sub-)ileus in advanced ovarian cancer

- (Sub-)ileus is a significant and often lethal complication in advanced ovarian cancer
- There is no standardized approach
- Concept: retrospective collection of all cases at the 6 BZKF sites in a given 2-year period
- Aim: to harmonize treatment strategies
- A register with all necessary items has already been developed by the study group

Biomarker research: STING/IFN-y response Primary Endpoints: Tumor marker CA125 Feasibility of PARPi Exploratory analysis rechallenge Reasons for/against PARPi rechallenge Liquid biopsies d0, d14, d28 Which PARPi is chosen and why? Secondary/explorative endpoints: Quality of life / (S)AEs: Quality of life **EORTC QLQ-C30 EORTC QLQ OV28** Documentation of the previous course TTTS, PFS, PFS1

DOR, PFS2, OS, OS2

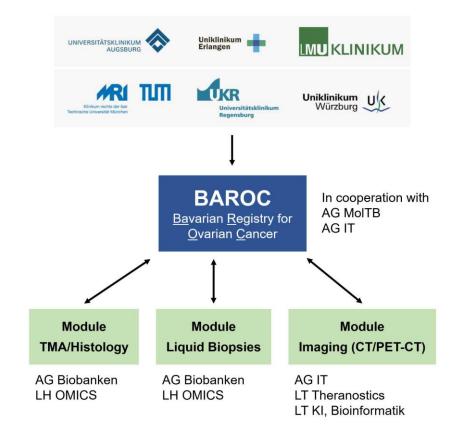
Project 3:

Retrospective/prospective registry for all ovarian cancer cases (Bavarian Registry for Ovarian Cancer, BAROC)

- Aim: to establish a comprehensive database for all ovarian cancer cases at the 6 BZKF sites
- The entire course of the disease will be mapped
- · The database and all individual items have already been developed in agreement with all 6 BZKF centers
- Programming of the database is currently ongoing
- First proposed analyses (,use cases'):
 - ORR and DOR to non-platinum chemotherapies in heavily pretreated ovarian cancer
 - MTB-based therapies (in coordination with AG MolTB)

BZKF network:

All 6 centres actively participate in the specified projects with representatives from gynecology, medical oncology and pathology. The BZKF-OVAR 1 study has proven to be an ideal use case to establish coordination among each other and with other working groups (biobank, data protection, IT). Networking with other BZKF units (e.g. Imaging/Theranostics Lighthouse) is aimed at in the upcoming funding period:



Future Milestones

- BZKF-OVAR 1:
 - First patient in' at each site until Q4/2023
 - Recruitment of 100 patients until Q3/2025
 - Analyses of predefined biomarkers, QoL and 3-6 month recurrence-free survival until Q4/2025
- BAROC registry: integration of CT/PET-CT imaging and biobanking modules
- Publications: BZKF-OVAR 1 (primary endpoints), BAROC (e.g. ,later lines' subproject), lleus project
- Development of new projects and clinical trials within the BZKF network

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