with promising results. Isolated thoracic perfusions, abdominal perfusions, and pelvic perfusions for primary and metastatic lesions of TNBC have shown to achieve high local drug concentrations and lesions' volume reduction to eligibility for resection. The combination with chemofiltration further decreases adverse events.
The IPAF-Breast1 trial evaluates the local response rates and regain of resectability of primary tumors and metastases as the primary objective. The secondary objectives are to evaluate the procedure related and chemotherapy induced side effects, the quality of life, the progression free survival and the overall survival.
Locally advanced and metastasized TNBCs show the need for new treatment options that increase the eligibility for surgical excision of primary tumors and metastases.
Materials and Methods: IPAF-Breast1 is a phase II prospective trial. It is open and non-randomized. Patients with histologically confirmed triple negative breast cancer at advanced stage are eligible. The primary endpoint is the local response rate. Secondary endpoints are procedure and chemotherapy related side effects, quality of life, progression free survival, and overall survival. Exploratory endpoints are the systemic immune response, changes of the tumor microenvironment with T-cell infiltration and PD-L1 expression, change of circulating tumor cells and circulating tumor DNA, and the effect of prior irradiation on local response. Six treatment cycles of isolated perfusions with perfusion balloon catheters in the aorta and vena cava that enable an isolated circuit are performed and followed by chemofiltration. Radiological response evaluations are done after every two cycles. Blood controls are done on day 0, 3, and 5 of each treatment cycle. Circulating tumor cells and circulating tumor DNA analysis is done on day 0 (each cycle). Tumor tissue is tested on the tumor microenvironment, tumor infiltrating lymphocytes, macrophages and PD-L1 expression. Each cycle consists of either: Isolatd Thoracic Perfusion, Hypoxic Abdominal Perfusion, Upper Abdominal perfusion, or Hypoxic Pelvic Perfusion. The number of sites will be 2-5. The enrolment time for 75 patients is 24 months and the follow-up period will be 24 months.
Results: Feasibility: IPAF-Breast1 is an Investigator Initiated trial funded by grants. The primary trial site is Burghausen in Germany. Further trial sites can be included.
Conclusions:

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CINDERELLA TRIAL: VALIDATION OF AN ARTIFICIAL-INTELLIGENCE CLOUD-BASED PLATFORM TO IMPROVE THE SHARED DECISION-MAKING PROCESS AND OUTCOMES IN BREAST CANCER PATIENTS PROPOSED FOR LOCOREGIONAL TREATMENT

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Background: Breast cancer therapy has made significant progress in improving overall survival rates, with different surgical approaches offering patients similar locoregional control but varied aesthetic outcomes. Given the high burden of consequences, it is crucial to prioritise improving patients' quality of life (QoL). However, addressing these problems has been challenging. To tackle this issue, the CINDERELLA Project aims to develop an easy-to-use, cost-effective artificial intelligence (AI) tool to aid shared decision-making by showing breast cancer patients the predicted aesthetic outcomes of locoregional treatment. The clinical trial will evaluate the use of an AI cloud-based platform approach (CINDERELLA App) containing the predicted images versus a standard approach prior to therapy. The trial's primary objective is to assess the levels of agreement among patients' expectations regarding the aesthetic outcome before and 12 months after treatment in both arms. Furthermore, the trial will evaluate the level of agreement about the aesthetic outcome between the AI evaluation tool and self-evaluation after treatment in both arms. We anticipate that the CINDERELLA App will lead to higher satisfaction, better psychosocial well-being and health-related QoL - all while maintaining the quality of care and providing environmental and economic benefits.
Materials and Methods: The clinical trial will be an open international randomised trial with parallel groups to compare the intervention arm using the CINDERELLA App with the control arm using the classical approach. Randomisation will be performed centrally, 1:1, to the control arm or intervention arm. The breasts of all included patients will be photographed prior to any treatment. In addition, all patients will complete questionnaires regarding their expectations, a consumption survey, and standard patient-reported outcome measures. The questionnaires and photographs will be repeated after the healing process, at six months and one year following the completion of treatment. For the trial's primary objectives, models of the class of generalised linear mixed models will be used to evaluate the effect of the training and women's characteristics on their evaluation of the aesthetic outcome of the surgery. The Wilcoxon signed rank test for pairs will also be used to evaluate the effect of training on the level of agreement of the expectations and the final result. Administered questionnaires will be scored according to their provided guidelines. Between June 2023 and June 2025, a minimum of 515 patients will be enrolled in each arm of the trial.
Results: Clinical trial recruitment will start in June 2023.
Conclusions: The CINDERELLA Project is funded by the European Union. The clinical trial is registered on ClinicalTrials.gov (identifier no. 05196269) and will mainly target the following countries: Germany, Italy, Israel, Poland and Portugal.

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THE USE OF LOW-MOLECULAR-WEIGHT HEPARINS AS PROPHYLAXIS IN CANCER SURGERY PATIENTS - A REGISTER-BASED RESEARCH PROGRAM IN SWEDEN

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Background: As patients undergoing cancer surgery are at a higher risk of developing venous thromboembolism (VTE), guidelines recommend anticoagulant prophylaxis with low-molecular-weight heparins (LMWH). Information about prophylaxis patterns of LMWH and outcomes in patients after cancer surgery in Swedish clinical practice is scarce. Knowledge about to what extent treatment guidelines are followed is also lacking. Swedish health care registers provide a unique opportunity to investigate treatment patterns and outcomes in the total Swedish population. An overall objective of this research program is to explore the extent of LMWH use as prophylaxis among Swedish cancer surgery patients. Specifically, the objective is to analyse the prophylaxis patterns and outcomes in terms of major bleedings, VTE and mortality in use of LMWHs in different patient populations (e.g. cancer surgery patients with urogenital, gastrointestinal, and gynecological cancers)