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Identification of New Biomarkers in Patients with Pancreatic Cancer (BIOPAC): A Study Protocol of an Open Cohort Study

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Background:
The overall survival of patients with pancreatic cancer (PC) is dismal and has improved only slightly during the last decades. Early detection of PC is difficult, and less than 25% of all patients with PC are eligible for surgery. No validated biomarkers exist that identify PC at an early stage and predict treatment outcomes in the individual patient. The objective of the present study is to find diagnostic, prognostic and predictive biomarkers that can be used (1) to diagnose PC with high specificity and sensitivity early in the course of the disease, (2) to improve prognostication, and/or (3) to predict and monitor treatment effectiveness and tolerability for the individual patient.

Methods and analysis:
Observational and translational open cohort study with prospective collection of biological materials and clinical data during all stages of the routine care of patients with PC and including patients with suspected pancreatic malignancy disproved after surgery. Blood samples are collected sequentially during the course of a patient's treatment: before surgery, at start of adjuvant or palliative chemotherapy as well as during treatment until disease progression. The patients are followed until death. Demographics, disease characteristics, comorbidities and lifestyle factors are registered at inclusion and weight and performance status in association with each treatment cycle. Routine blood tests (i.e., haematology, creatinine, liver enzymes, bilirubin, and carbohydrate antigen 19-9, C - reactive protein) are collected at regular intervals, and type of operation, chemotherapy and number of cycles given, date of disease recurrence in patients subjected to surgery, date of disease progression for each line of chemotherapy and date of death are recorded.

Currently in July 7, 2019 a total of 5156 samples from 2141 patients have been collected.

Discussion:
Biomarker analyses include a range of molecules such as deoxyribonucleic acid (DNA), single nucleotide polymorphism (SNPs), ribonucleic acid (RNA), microRNA, proteins and metabolites. Data will be analyzed using appropriate methods and statistical analyses.

Conclusion: It is our hope that this ongoing study will provide new information on biomarkers and will contribute to precise treatment options for patients with PC in order to improve outcomes.

Trial Registration: ClinicalTrials.gov ID: NCT03311776. The trial was registered retrospectively; registration date 10/06/2017. Ntative.