Background
Due to the overall poor prognosis of pancreatic adenocarcinoma, neoadjuvant therapy is being increasingly studied in the treatment of pancreatic adenocarcinoma across all anatomic surgical categories.

Aim
The aim of the PIOPPO trial is to assess the role of combination neoadjuvant chemotherapy (NACT) followed by carbon ion hadrotherapy (CIRT) for patients with resectable or borderline resectable pancreatic cancer. The primary endpoint of PIOPPO trial is local progression free survival and secondary endpoints are overall survival, R0 resectability rate and treatment toxicity (including intra and perioperative toxicity).

Methods
PIOPPO is a prospective, phase II, multicentre and single-arm study.
Thirty patients will be enrolled in the study, the sample size being defined with an expected probability of success proportion of success at 24 months of 60% vs 35% (H0: p <= 0.35-H1: p > 0.35). Enrolled patients with a resectable or borderline resectable pancreatic cancer underwent to 3 cycles of FOLFIRINOX followed by CIRT at the dose of 38.4 Gy [RBE] carried out in 8 fractions, 4 fractions per week. 4D and breath gated planning is performed and rescanning is carried out. GTV is established using CT, MRI and PET images. CTV is defined as GTV with 5 mm margin, locoregional elective lymph node and neuroplexus region. From 4 to 6 weeks after completion of CIRT patients will undergo conventional pancreatic surgery. Subjects who meet the enrolment criteria but eventually decline to participate in the study will serve as controls. In the post-operative period, adjuvant chemotherapy is given according to clinical practice.

Results
Since January 2018 six patients have been so far enrolled and five have completed the surgical phase. No significant acute toxicity, including surgery-related was observed.

Conclusions
Our results provide initial evidence of the feasibility of the combined chemotherapy and CIRT in the neoadjuvant setting for resectable or borderline -resectable pancreatic cancer.