



PETACC 8

ADJUVANT TREATMENT OF FULLY RESECTED STAGE III COLON CANCER WITH FOLFOX-4 *VERSUS* FOLFOX-4 PLUS CETUXIMAB

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Sponsor and Coordinating group

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1. SYNOPSIS

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| Title of study | PETACC 8: ADJUVANT TREATMENT OF FULLY RESECTED STAGE III COLON CANCER WITH FOLFOX-4 <i>VERSUS</i> FOLFOX-4 PLUS CETUXIMAB |
| Study endpoints | <ul style="list-style-type: none"> • <u>Primary</u>: Disease free survival • <u>Secondary</u>: <ul style="list-style-type: none"> - 3-year disease free survival rate - Overall survival - Treatment compliance - 5-year overall survival rate - Identification of prognostic factors - Safety - Translational research for evaluation of markers predictive for relapse and/or treatment efficacy. |
| Main Inclusion Criteria | <ul style="list-style-type: none"> - Age \geq 18 and $<$75 - Pathologically confirmed stage III adenocarcinoma of the colon, regardless of EGFR status, - Curative R0 resection performed between 28 and 56 days prior to randomization - No prior chemotherapy - No prior abdominal or pelvic irradiation - WHO performance status: 0 or 1 - Signed written informed consent obtained prior to any study specific screening procedures - Patients with childbearing potential should use effective contraception |
| Main Exclusion Criteria | <ul style="list-style-type: none"> - Distant metastatic disease - Inflammatory bowel disease - Rectal cancer located within 15 cm from the anal verge by endoscopy or under the peritoneal reflection at surgery or having received radiation therapy prior to surgery - Pregnant or breast-feeding woman - Neuropathy - Known hypersensitivity reaction to any of the components of study treatments. |
| Study design and treatment plan | <p>This open randomized, controlled, multinational/multicenter European phase III study is setting to evaluate the efficacy of cetuximab in addition to FOLFOX-4 for 6 months in patients with fully resected colon cancer.</p> <ul style="list-style-type: none"> - Arm A: FOLFOX-4 alone every 2 weeks - Arm B: Cetuximab every week + FOLFOX-4 every 2 weeks. <p>The cycle duration in Arms A and B is 14 days (2 weeks) with a total of 12 planned cycles (24 weeks). Patients will be followed for recurrence/new occurrence of colon cancer and survival.</p> <p>Randomization will be stratified according to:</p> <ul style="list-style-type: none"> No obstruction and no perforation vs obstruction and/or perforation T1-3 vs T4 N1 vs N2. <p>Time for Randomization: d28 to d56 after surgery. Maximal period between randomization and treatment = 14 days.</p> |