CAPECITABINE PLUS IRINOTECAN VERSUS 5-FU/FA/IRINOTECAN +/- CELECOXIB IN FIRST LINE TREATMENT OF METASTATIC COLORECTAL CANCER (CRC). LONG-TERM RESULTS OF THE PROSPECTIVE MULTICENTER EORTC PHASE III STUDY 40015
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For the EORTC Gastro-Intestinal Tract Cancer Group

STUDY DESIGN

METHODS

FOLFIRI (Doulard’s regiment)

Triﬂuridone IV 100 mg/kg, 30-39, 40-49, 50-59, 60-69, 70-79 years
Levamisole IV 5 mg, given on 1, 8, 15, 22, 29, 36
S-Triﬂuridone IV 100 mg/kg, 30-39, 40-49, 50-59, 60-69, 70-79 years

Original Sample Size: 692 patients

Non-hematological toxicity

Blood pressure......

Hematological toxicity

CAPIRI

PLACEBO / CELECOXIB

X 600 mg
Daily

MAIN ELIGIBILITY CRITERIA

- metastatic disease previously untreated with chemotherapy
- no previous chemotherapy treatment except if completed at least 6 months prior to randomization
- no concurrent or planned concomitant therapy with NSAIDs or COX-2 inhibitors
- adequate bone marrow, renal and liver functions
- no HIV infection
- no multiple malignancies, uncontrollable severe medical condition
- informed consent

INITIAL OBJECTIVES

- to demonstrate that CAPIRI is non-inferior to FOLFIRI in terms of progression-free survival
- to demonstrate that celecoxib improves progression-free survival compared to placebo
- to demonstrate that celecoxib improves time-to-progression-free survival compared to placebo

WORST ADVERSE EVENTS (patients who started CT, CTC/A version 2.0)

BEST OVERALL RESPONSE

DESCRIPTION OF TOXIC DEATHS (early and other)

CONCLUSION