

Abstract

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Background: Induction chemotherapy (IC) followed by chemoradiation (CRT) is an attractive approach in locally-advanced, high-risk rectal cancer. Additionally, aspirin has shown potential to lower recurrence rate in colorectal cancer, and improve outcomes alongside CRT in rectal cancer, with higher rate of tumor downstaging. **Methods:** Randomized, double-blind phase 2 trial to evaluate induction treatment with XELOX, followed by capecitabine-based chemoradiotherapy with aspirin or placebo in a high risk population selected by MRI. The aim of this study was to evaluate MRI response after total neoadjuvant treatment with aspirin or placebo. **Results:** Of the 25 pts who started treatment between January 2018 and March 2019, 4 pts did not complete (1 pt grade 5 diarrhea; 1pt treatment adherence). Median age was 55yo (32.9 - 73.6), 8 pts (32%) were women, and 80% had 3 or more high-risk criteria. 20 pts (80%) showed symptom improvement in the first cycle of IC. Of the 21 patients who finished treatment until interim analysis, 11 pts received aspirin (2 pts had MRI complete response (CR), 3 pts had minor/no response, and 3 pts had progression disease (PD)). 10 pts received placebo (4 MRI CR, 3 pts had minor/no response, and no PD). **Conclusions:** Aspirin added to chemoradiotherapy was safe but did not improve response to total neoadjuvant treatment. The study was closed due absence of benefit. [Clinical trial information: NCT03170115](https://clinicaltrials.gov/ct2/show/study/NCT03170115).