

Genistein Combined With FOLFOX or FOLFOX-Avastin for Treatment of Metastatic Colorectal Cancer: Phase I/II Pilot Study - SAP

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Comparison will be with historical data on the response rate as documented in a previously published large phase III study which compared a standard oxaliplatin and 5FU combination (FOLFOX) to the same combination with the addition of avastin (FOLFOX-Avastin) [Saltz LB, et al. Bevacizumab in Combination With Oxaliplatin-Based Chemotherapy As First-Line Therapy in Metastatic Colorectal Cancer: A Randomized Phase III Study. 2008 JCO:2013-2019]. Both arms of this study had response rates of 38%. Equal distribution of males and females is anticipated.

The published response rates (RR) to FOLFOX and FOLFOX-A are 38%. In order to achieve a 20% increase in RR (to 46%) with a power of 0.8 at a level of significance of $p<0.05$ (two tailed), 24 patients will need to be treated. Since FOLFOX and FOLFOX-Avastin have identical RR, both groups will be analyzed together for RR. However, progression-free survival (PFS) is longer for FOLFOX-Avastin than FOLFOX alone (ie, avastin helps in preventing progression but does not improve the response to chemotherapy) so analysis will be stratified for this secondary endpoint and also for toxicity evaluation. Response rate will be compared to previously published data.