

Research Unit Scientific Presentation

Unit of Medical Oncology

The **research activity** of the Unit of Medical Oncology is carried out mostly through the conduction of profit and no-profit clinical studies in different tumor types. At present, we are conducting 11 spontaneous clinical studies and we are also participating to 10 sponsored trials in lung, colorectal, renal and breast cancer responding to the rules of Good Clinical Practice.

In particular, we have coordinated a randomized phase III multicentric clinical study, conducted by the Gruppo Oncologico Nord Ovest (G.O.N.O.), that has compared an experimental biweekly regimen with Irinotecan (CPT-11), Oxaliplatin (L-OHP) and infusional 5-Fluorouracil (5-FU)/Leucovorin (LV) (FOLFOXIRI) with a standard biweekly regimen of CPT-11 and infusional 5FU/LV (FOLFIRI) in patients with metastatic colorectal cancer. The primary end-point was response rate, secondary end-points were progression free-survival, post-CT R0 surgical resections and overall survival. Two-hundred and forty-four patients have been randomized. Final results have demonstrated a significantly higher response rate (60% vs 34%, $p < 0,0001$) and a longer progression free survival (PFS) (median 9,8 vs 6,9 months, $p = 0,0006$) of the FOLFOXIRI arm, with manageable toxicities, compared to control arm. Although data are still immature, overall survival is also significantly improved with FOLFOXIRI with a relative reduction in the risk of death of 30% and an absolute improvement in median survival of 5,9 months (median 22,6 vs 16,7 months, $p = 0,032$). Furthermore, in the patients with only liver metastasis (42 in the FOLFIRI arm and 39 in the FOLFOXIRI arm), a significantly higher post-CT R0 surgical resections was possible in the experimental arm FOLFOXIRI (36% vs 12%, $p = 0,017$). In conclusion, the study has demonstrated that response-rate, progression free survival, overall survival and post-CT radical surgical resection of metastasis are improved with FOLFOXIRI respect to a standard two drug combination as CPT-11 plus infusional 5-FU/LV. In the figure are reported the actuarial overall survival curves of the two treatments.

