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Background: Advanced hepatocellular carcinoma (HCC) not amenable to local therapies has limited chances of cure and has a poor prognosis. Sorafenib is a multikinase inhibitor with proven activity in advanced HCC. Octreotide is already used in this setting with conflicting but usually interesting results.

Methods: An original schedule with sorafenib and long-acting octreotide is currently tested in advanced HCC enrolled from different institutions. Sorafenib is administered at a dosage of 400 mg/daily for 28 d with a following week of rest. Ten days after starting sorafenib, long acting octreotide is administered at a dose of 40 mg with monthly scheduled administrations. Objectives of this study are the evaluation of activity and potential toxicity of the treatment. Tumor response is assessed bimontly.

Results: At the date of 28 April 2008, 57 patients were considered for study entry and 42 were enrolled (sex: 33M/9F; age range: 57–80 years; HCV: 26 patients, HBV: 10 patients, HCV + HBV: 1 patient; unknown etiology: 5 patients; child A/B: 31/11). Patients naïve from other therapies were 19, whilst all the others were previously treated with local and/or systemic treatments. Three patients were not evaluable because of premature treatment stopping caused by diarrhoea grade 3. Twenty-four patients were evaluated until now. Among 12 patients evaluable after 2 months of therapy, we registered 1 minimal response, 3 stable disease and 8 disease progression. Among 8 patients evaluable after 4 months, we reported 5 stable disease and 3 disease progression. Among 4 patients evaluable after 6 months, we reported 1 minimal response and 3 stable disease. Treatment was generally well tolerated apart from haemorrhoidal bleeding (2 patients), skin toxicity grade 2 and grade 3 in 2 patients, respectively, hypertension in 3 patients.

Conclusions: The association of sorafenib and long acting octreotide appears feasible in advanced hepatocellular carcinomas not susceptible of local therapies. Longer follow-up of this study is needed to evaluate clinical activity of this schedule.

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BI-WEEKLY ADMINISTRATION OF CAPECITABINE + OXALIPLATIN (XELOX-2) IN FIRST LINE TREATMENT OF ADVANCED COLORECTAL CANCER (ACRC): PRELIMINARY RESULTS

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Background: FOLFOX regimen represents a standard first line therapy for ACRC. Recent studies observed that tri-weekly XELOX administration is characterised by effectiveness and tolerance similar to FOLFOX 4 infusional schedule. This phase II multicenter study of the Gruppo Oncologcio dell'Italia Meridionale (GOIM) started to evaluate the activity and the toxicity of bi-weekly administration of capecitabine + oxaliplatin in ACRC patients.

Materials and methods: Thirty-two advanced colorectal cancer pts with measurable disease, ECOG PS $\leqslant$ 2, age 18–75 years (yrs) were enrolled. The schedule of treatment was as follows: oxaliplatin at 100 mg/mq i.v. on day 1 and capecitabine at 2000 mg/mq p.o. in a two daily administration from days 1 to 7, every 2 weeks. The recist and NCI criteria were employed to determine the activity and the toxicity of this combination, respectively.

Results: At present, 32 patients have been enrolled and up to now 29 of them are evaluable for activity and toxicity. The main characteristics were: sex (M/F) 23/9, median age 70 yrs (range 54–75), median PS 0, main sites of disease: liver 26 (81%), lymph-nodes 9 (28%) and lung 4 (12%). One CR (3%) and 12 PR (42%), 8 SD (27%) and 8 PD (27%) were observed. The main toxicity rate (G1–2 versus G3–4) were: thrombocytopenia 44/6, anaemia 41/0, nausea/vomiting 28/0, diarrhoea 22/0, neurotoxicity 50/0 and asthenia 16/3.

Conclusions: These preliminary data show that the bi-weekly administration of capecitabine + oxaliplatin is active and well tolerated by ACRC patients. This study is still ongoing.

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FOLFIRI VERSUS XELIRI IN UNTREATED ADVANCED COLORECTAL CANCER: A PHASE II RANDOMISED TRIAL OF THE GRUPPO ONCOLOGICO DELL' ITALIA MERIDIONALE (PROT. GOIM 2405)

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Background: Irinotecan (Cpt-11) plus fluorouracil (Fu) modulated by folinic acid (Fa) (folfiri regimen) is one of the standard first-line treatment in advanced colorectal cancer (ACC). The oral fluoropyrimidine xeloda (Xel) is equivalent in terms of efficacy and demonstrated a better safety profile than bolus Fu–Fa. Besides Xel can replace Fu continuous infusion. Also the combination of Cpt-11 plus Xel (xeliri regimen) demonstrated to be active as a first-line treatment in ACC patients. So the GOIM started a randomised multicenter phase II trial aiming to compare the activity and safety of folfiri and xeliri in this setting.

Methods: Untreated patients with histologically confirmed diagnosis of colorectal cancer entered into the trial if they satisfied the following inclusion criteria: presence of measurable disease (recist criteria), age > 18 years, performance status < 2 (Ecog scale), adequate bone marrow reserve and renal and hepatic function, informed written consent. The enrolled patients were randomised 1:2 to receive arm A: Cpt-11 at 180 mg/m^2 on day 1,