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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,

FA at 100 mg/m^2 as 2 h infusion on days 1–2, FU at 400 mg/m^2 as bolus on days 1–2 plus FU at 600 mg/m^2 as 22 h infusion on days 1–2 (folfiri) every 2 weeks, or arm B: Cpt-11 at 250 mg/m^2 on day 1 and xeloda 2000 mg/m^2 for 14 days (xeliri) every 3 weeks.

Results: Up to now 91 patients have been enrolled: 54 are evaluable for activity and toxicity (A/B: 20/34). The main characteristics of the evaluable patients are (A/B): median PS: 0/0; sites of disease: liver 12/26, lung 7/15, lymph-nodes 1/8, others 3/4. Among the evaluable patients we observed the following responses (A/B) CR: 1/0 (5/0%), PR: 4/18 (20/53%), SD: 11/11 (55/32%) and PRO: 4/5 (20/15%) for an ORR of 25% and 53%, respectively. Grades 3–4 haematologic toxicity (NCI criteria) were: neutropenia 15/21% and anaemia 5/3% whilst the main non haematologic side effect was diarrhoea observed in 5/18%, respectively.

Conclusions: Our preliminary results do not permit any definitive conclusion regard the activity of the two combinations. The toxicity profile of xeliri is similar to those of previous studies.

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BEVACIZUMAB + FOLFIRI AS FIRST-LINE TREATMENT IN ADVANCED COLORECTAL CANCER (ACC): A MULTICENTER PHASE II STUDY OF THE GRUPPO ONCOLOGICO DELL' ITALIA MERIDIONALE (PROT. GOIM 2601)

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Background: The addition of bevacizumab (BEV) to irinotecan (CPT-11) plus bolus fluorouracil (FU) and folinic acid (FA) (IFL regimen) demonstrated to be more active and more effective than chemotherapy alone in a randomised phase III trial. However IFL is considered more toxic than FOLFIRI regimen. So we started a phase II trial to evaluate the activity and the safety of the combination of BEV plus FOLFIRI as first-line therapy in ACC patients (pts).

Methods: Untreated pts with histologically confirmed diagnosis of colorectal cancer entered into the trial if they satisfied the following main inclusion criteria: presence of measurable disease, age > 18 years, performance status $\leqslant$ 2 (ECOG scale), adequate bone marrow reserve and renal and hepatic function, informed written consent. An history of cardiovascular disease, thromboembolic events and/or coagulative disorders were considered as exclusion criteria.

The enrolled pts were treated with CPT-11 at 180 mg/m^2 on day 1, FA at 100 mg/m^2 as 2 h infusion on days 1–2, FU at 400 mg/m^2 as bolus on days 1–2 and FU at 600 mg/m^2 as 22 h infusion on days 1–2 (FOLFIRI) plus BEV at the dosage of 5 mg/kg on day 1, every two weeks. A maximum of 12 cycles of chemotherapy was planned and a maintenance with BEV for 6 months was permitted. The evaluation of the activity (recist criteria) was performed every four cycles.

Results: Up to now 72 pts have been enrolled and 61 are evaluable for activity and safety (eleven pts are too early). The main characteristics of the evaluable pts were M/F: 32/29; median PS: 0 (range 0–2); median age 61 (range 33–73); primary site (colon/rectum): 40/21; main sites of disease: liver 45, lung 16, lymph-nodes 15, others 6; single site: 39 and multiple sites: 22.

Three CR (5%) and 25 PR (41%) were observed for an ORR of 46%; 26 pts had SD (43%) for an overall TGCR of 89%. Only 7 PRO (11%) were observed. The response rate according to site were: liver 21/45 (46.6%), lung 8/16 (50%). The only grades 3–4 toxicity (NCI criteria) were neutropenia 10% and thrombocytopenia 2%. Ten pts (16%) had hypertension but only one was uncontrolled by medical therapy and interrupted the study. One pts had epistaxis.

Conclusions: Our results indicate that the addition of BEV to FOLFIRI regimen is an active and well tolerated first-line treatment for ACC pts. Final data will be available for the meeting.

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RADIOCHEMOTHERAPY FOR ANAL CARCINOMA: OUR EXPERIENCE

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Background: Radiochemotherapy of anal carcinoma is an organ sparing approach with a high curative potential.

Patients and methods: Between August 1999 and June 2007, 18 patients were treated with external radiation therapy (RT) and concomitant chemotherapy (CT). The main characteristics of patients were: histology: 14 squamous carcinoma, 2 basaloid, 1 adenocarcinoma, 1 undifferentiated carcinoma; stage (2001 UICC classification): II 7 cases, III A 9, III B 2; age: median 61 year, range 33–79; sex (F/M): 10/8. RT was delivered at the whole pelvis with a four-field box technique followed by a boost at the primary tumour. The median dose of RT at the whole pelvis and at the primary tumours was 45 Gy and 55 Gy, respectively. CT was carried out during the first and last four days of RT with continuous infusion of 5-fluorouracil (1000 mg/m^2/day) plus bolus mitomycin C (10 mg/m^2 on day 1) in 16 patients or cisplatin (100 mg/m^2) in 2. After a rest period of 4-6 weeks two courses of cisplatin plus 5-Fluorouracil was delivered in 4 patients with locoregional advanced disease.

Results: CR were observed in 8 patients (44%), PR in 4 (22%), SD in 4, and PD in 2. Local recurrences occurred in 4 patients previously obtaining RC (1/8), RP (2/4), SD (1/4) and 2 of them were rescued by conservative surgery. Distant metastases occurred in two cases and inguinal failure in one. The median duration of response was 12 months (3–62) and the sphincter preservation rate was 90% (16 patients). Temporary interruption of the treatment as a result of acute toxicity (gastrointestinal) was necessary in 3 patients. With a median follow up of 17 months (range 5–57), 10 patients are alive and 9 disease-free. Eight patients died due to a progressive disease (locoregional failure in 5 patients, liver metastases in 2, lung metastases in 1).