- Record patient episode data and associated applied Tacit Knowledge used by Consultant Oncologists during the clinical management of patients diagnosed with advanced breast cancer
- Provide a knowledge resource for oncologists in the domain of advanced breast cancer
- Propose similar episodes of patient care for patients attending outpatient clinics
- Provide an '*ask the expert*' service where junior oncologists can provide anonymous patient data and request advice from acknowledged experts.

It will be fully prototyped and experimented within the key clinical process of cancer care, addressing the substantial problems of bridging clinical expertise between secondary (hospital) care and after care led by the general practitioner and supporting specialist community nurses.
Thus the innovations arising from the project will be piloted and fully validated in two European hospitals, leading to a strong set of case studies and results which will be disseminated to the healthcare and Information and Communication Technologies communities, and to the wider European research area.
This project has been partially funded by the European Commission under the IST initiative.

References

[1] http://oncology.fecs.be

Gastrointestinal Tumours

Oral presentations (Wed, 2 Nov, 9.15–11.15)

GI – metastatic colon cancer

597 ORAL

A randomised phase III multicenter trial comparing irinotecan in combination with either the Nordic bolus 5FU and folinic acid (5FU/FA) schedule (FLIRI) or the bolus/infused de Gramont schedule (FOLFIRI), in patients with metastatic colorectal cancer

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Background: Irinotecan with FU/FA is an established regimen in metastatic colorectal cancer, however, with major uncertainties related to the mode of administration of FU. In the US, a weekly bolus schedule, the Saltz regimen, was used extensively, whereas in Europe, infused 5FU is preferred. We have compared irinotecan in combination with either the Nordic fortnightly 5FU/FA bolus schedule (FLIRI) or the fortnightly Lv5FU2 schedule (FOLFIRI).
Methods: Between August 2001 and March 2004, 567 previously untreated patients with metastatic colorectal cancer at 27 centres in the Nordic countries were randomized to either FLIRI (irinotecan 180 mg/m^2 day 1, 5FU 500 mg/m^2 bolus iv day 1, 2, FA 60 mg/m^2 day 1,2) or FOLFIRI (irinotecan 180 mg/m^2 day 1, FA 200 mg/m^2 day 1, 2, 5FU bolus 400 mg/m^{2}day 1, 2 and infused 5FU 1200 mg/m^2 per 48 hour). The dose of irinotecan, found in a preceding phase II study with the Nordic schedule (210 mg/m^2) was lowered after the first 100 randomized patients to 180 mg/m^2 because of a slight excess of toxicity (any grade 3–4, 49 vs 38 instances, 60 day mortality 3 vs 2) and concerns seen using the Saltz regimen in two American trials. The primary endpoint was progression-free survival with the aim to show non-inferiority (at the most 20% worse or from median 6.7 to 5.4 months, $\alpha = 0.05$, $1 - \beta = 0.80$).
Results: Patient characteristics were well balanced between groups. In the entire patient material, including the first 100 patients, toxicity did not differ between groups (grade 3/4 nausea/vomiting 20 vs 37, diarrhea 23 vs 31, neutropenia 19 vs 8, fever 11 vs 14). The 60 day mortality was 2.4% vs 2.3% (6 patients each in both groups). The primary endpoint, time to progression, did not differ between groups (median 9.1 months in both groups, $p = 0.34$).
Conclusions: Irinotecan with the bolus FU/FA Nordic schedule (FLIRI) is a convenient treatment with efficacy and toxicity comparable to the 'infused' FOLFIRI regimen. Response rates and overall survival will be presented at the meeting.
The work was supported in part by Aventis.

598 ORAL

Randomised comparison of 5-FU/folinic acid plus irinotecan (FOLFIRI) and irinotecan plus oxaliplatin (IROX) in first-line therapy of metastatic colorectal cancer (CRC): the fire-trial

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Objective: This randomised trial compares the 1st-line efficacy and toxicity of infusional 5-FU/FA (AIO regimen) plus irinotecan (FOLFIRI) to the combination of irinotecan plus oxaliplatin (IROX).
Methods: 488 patients (pts) from 56 centres were enrolled between July 2000 and the end of study in September 2004. In the FOLFIRI arm, pts received FA 500 mg/m^2 plus 5-FU 2000 mg/m^2 (24h) and irinotecan 80 mg/m^2 given weekly for 6 times. In the IROX arm pts were treated with oxaliplatin 85 mg/m^2 (d1, 15, 29) and irinotecan 80 mg/m^2 weekly times 6. Treatment cycles were repeated on day 50 in both treatment arms. Patients were stratified according to LDH, adjuvant pretreatment, and Karnofsky performance status (KPS) showing LDH >240 U/ml in 42% vs 39%, adjuvant pretreatment in 31% vs 29%, and a KPS = 100% in 48% vs 47%, in the FOLFIRI- and IROX-arm respectively. The primary end-point of the trial was progression-free survival. At disease progression, pts were offered to switch to the comparator regimen.
Results: Treatment efficacy was evaluable in 478 pts (240 FOLFIRI, 238 IROX). Second-line therapy according to the cross-over protocol was FOLFIRI) of patients. The IROX and 29% (IROX documented in 33% (FOLFIRI complete remission rate (CR) was 7.9% vs 8.3%, the partial remission rate (PR) 36.7% vs 39.5% for an overall remission rate (CR+PR) of 44.6% vs 47.8% in the FOLFIRI- and IROX-arm, respectively. Stable disease (SD) was documented in 44.2% vs 30.7%. Median progression-free survival was 8.2 months vs 7.0 months ($p = 0.377$) with a hazard ratio of 1.093 (95%CI: 0.897–1.330), while median overall survival was 21.9 months vs 19.3 months ($p = 0.249$) with a hazard ratio of 1.159 (95%CI: 0.902–1.49). 60-day mortality was 6.3% and 4.2% (FOLFIRI vs IROX).
Conclusions: FOLFIRI and IROX are comparably effective with regard to response, progression-free survival, and overall survival. Toxicity is similarly acceptable in both treatment arms.

599 ORAL

Improved activity with irinotecan, oxaliplatin and infusional 5-FU/LV (FOLFOXIRI) compared with FOLFIRI in metastatic colorectal cancer (MCRC): results of a randomized Phase III trial by the Gruppo Oncologico Nord Ovest (G.O.N.O.)

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Background: The FOLFOXIRI regimen has demonstrated promising antitumor activity coupled with manageable toxicities in Phase II trials in MCRC.
Patients and methods: 244 patients (pts) with measurable, not resectable MCRC and previously untreated with chemotherapy (CT) for advanced disease, were randomly assigned to receive: irinotecan 180 mg/sqm d1, l-LV 100 mg/sqm d1+d2, 5FU 400 mg/sqm bolus d1+d2, 5-FU 600 mg/sqm 22-h infusion on d1+d2 (FOLFIRI, arm A, n = 122) or irinotecan 165 mg/sqm d1, oxaliplatin 85 mg/sqm d1, l-LV 200 mg/sqm d1, 5FU 3200 mg/sqm 48-h infusion starting on d1 (FOLFOXIRI, arm B, n = 122). Both treatments were repeated every 2 weeks and after progression to FOLFIRI an oxaliplatin containing regimen was recommended.