lung cancer, renal cell carcinoma and melanoma. Primary endpoints are to assess the safety and tolerability of escalating single doses and of escalating multiple doses of s.c. administered MGN1703, to determine the maximum tolerated dose (MTD) and dose limiting toxicity (DLT), and to recommend a dose for a phase II trial in patients.
Results: Currently, 12 patients have been treated and evaluated in the single dose groups of 0.25 mg, 2 mg, 10 mg and 30 mg (3 patients each). In the multiple dose group, 4 patients have been treated with 0.25 mg, 3 patients with 2 mg, 3 patients with 10 mg and 3 patients with 30 mg MGN1703, so far. Therapy was well tolerated except for sporadic transient symptoms like mild redness or induration of the injection site in 2 patients, increase of temperature to 38 degrees C in 1 patient, and mild fatigue in 2 patients. In the 0.25 mg group, 1 patient showed a SD after 6 weeks of treatment, and in the 2 mg group, 3 of 3 patients showed a SD after 6 weeks. Treatment results of the last 2 dosing groups are pending. The four responded patients were treated with MGN1703 for further 6 weeks within the extension phase of this clinical trial. Two of them had a SD after 12 weeks of treatment.
Conclusions: MGN1703 showed safety and tolerability at dosages up to 30 mg, so far. The detailed evaluation of clinical and immunological responses is still ongoing. There has been no DLT at this point of the Phase I trial.

45LBA LATE BREAKING ABSTRACT

Early results of randomized phase II trial of preoperative chemoradiotherapy or short-term radiotherapy for stage II and III rectal cancer followed by radical delayed (with 6 weeks interval) surgery

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Background: The mostly accepted preoperative treatment methods for locally advanced rectal cancer are concomitant chemoradiation (CTRT) followed by interval surgery or short term radiation (25 Gy, 5 fractions) (RT) followed by immediate surgery. There are no data from randomized trials regarding the effectiveness of short term radiation followed by delayed surgery. The aim of this study was to compare operative and pathological results after short-term radiotherapy or concomitant chemoradiotherapy followed by delayed surgery.
Material and Methods: 79 patients with stage II and III (resectable T3−4 N0 and T1−4N1−2) rectal adenocarcinoma were enrolled. 46 patients received concomitant chemoradiotherapy (50 Gy + 5-fluorouracil 400 mg/m2/d 1−4 d. on weeks 1 and 5 and leucovorine 20 LV mg/m2/d 1−4 d on weeks 1 and 5) and 33 received short-term radiotherapy (5 × 5 Gy). Surgery was performed 6 weeks after preoperative treatment in both groups. This study is still recruiting patients. Trial is registrated in website ClinicalTrials.gov, Identifier NCT 00597311.
Results: R0 resection rate was 91% in the CHRT group and 90% in the RT group ($p = 0.734$). Sphincter preservation rates were 67% vs 75% ($p = 0.578$) and postoperative complications rates were 26% vs 39% ($p = 0.326$) accordingly. There was no differences in postoperative pathological T and N stage, lymphatic and vascular invasion. Tumors were smaller after preoperative CTRT (2.4 cm vs 3 cm; $p = 0.04$). A mean of 9.7 lymph nodes per specimen were detected in the RT group and significantly fewer lymph nodes were detected in the CHRT group – 6.13 ($P = 0.001$).
Conclusions: Interim analysis of the trial data showed that preoperative chemoradiation resulted in statistically significant tumor downsizing comparing with short term radiation, but there were no difference in the rates of R0 resection and sphincter preservation between the two groups. Preoperative chemoradiotherapy resulted in fewer lymphnodes detected in the tumor-bearing specimen compared with short-term radiotherapy, with no differences in T and N stage.

46LBA LATE BREAKING ABSTRACT

15-years follow-up results of the randomized Dutch D1D2 Trial: lower cancer-related mortality after D2

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Background: A nationwide randomized clinical trial to study whether standardized D2 lymphadenectomy results in better survival rates compared with standardized D1 lymphadenectomy in patients with resectable gastric cancer, based on superior results after D2 lymphadenectomy in historical data and reports from Japan.

Material and Methods: Between August 1989 and July 1993, a total of 996 eligible patients were entered in the study. Of these patients, 711 (380 in the D1 group and 331 in the D2 group) underwent the randomly assigned treatment with curative intent and 285 underwent palliative treatment. At the time of the trial, resection of the spleen and pancreatic tail were regarded as necessary for adequate removal of D2 lymph node stations 10 and 11 in proximal tumors and in D1 in case of tumor invasion. Strict quality control measures for surgery and pathology were implemented and monitored. Data were collected prospectively and all patients were followed: Median follow-up for all eligible patients is 15.2 years (range, 6.9 to 17.9 years). This analysis focuses on the 711 patients treated with curative intent.
Results: Of the 711 patients treated with curative intent, one-hundred seventy four patients (25%) are still alive, all but one without recurrence. Overall 15-year survival rates for D1 and D2 are 22% and 28% respectively ($p = 0.35$). With 5-year survival rates of 45% and 47% and 11-year survival rates of 30% and 35% for D1 and D2 respectively, the results are the best recorded survival rates in Western countries.
Cause of death was further specified (see table below): gastric cancer related death rate was significantly higher in the D1 group compared with the D2 group, while death due to other diseases was similar in both groups. Local recurrence (22% in D1 vs. 12% in D2) and regional recurrence (19% in D1 vs. 13%in D2) was more frequent in patients after D1.

	Dissection		p-value
	D1 (n=380)	D2 (n=331)	
Cause of death			0.003
Alive	82 (22%)	92 (28%)	
Gastric cancer	182 (48%)	123 (37%)	
Other diseases	94 (25%)	77 (23%)	
Toxicity treatment	15 (4%)	32 (10%)	
Unknown	7 (2%)	7 (2%)	

Conclusions: Considering the superior cancer related death rates and recurrence patterns, and with a safer, spleen preserving D2 resection technique nowadays available in high volume centers, D2 is the recommended way to go in patients with resectable (curable) gastric cancer.
The outcome of the randomized Dutch D1D2 trial will change a D1 dissection as standard treatment into a D2 dissection for patients with gastric cancer as standard treatment in daily practice.

47LBA LATE BREAKING ABSTRACT

Phase II trial of sorafenib with capecitabine and oxaliplatin (SECOX) in patients with locally advanced or metastatic hepatocellular carcinoma

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Background: This is a single arm, multi-centre, phase II study to assess the efficacy and tolerability of sorafenib combining oxaliplatin and capecitabine for the treatment of advanced hepatocellular carcinoma (HCC) patients.
Methods: Advanced HCC patients with no prior systemic therapy received SECOX regime – sorafenib 400 mg bid (Day 1−14), oxaliplatin 85 mg/m^2 (Day 1) and capecitabine 1700 mg/m^2 (Day 1−7) every two weeks. Response assessment using RECIST criteria was performed after 4 cycles. Patients who achieved partial response or stable disease would receive another 4 cycles till a maximum of 8 cycles. Afterwards, sorafenib was continued till disease progression. The primary endpoint was time-to-progression (TTP) and the secondary endpoints were tumor response rate (RR), overall survival (OS) and tolerability.
Results: A total of 51 patients were enrolled in the trial. The median age was 58 years (range, 28−81) and all patients were in ECOG Performance Status 0−1. Eighty-four percent of patients were chronic hepatitis B carriers and 98% of patients had Child A cirrhosis. Ten (20%) patients had tumor vascular invasion and 41 (80%) patients had extra-hepatic metastasis. The best RR was 14 % and another 61% of patients achieved stable disease. Overall, 75% of patients derived clinical benefits from SECOX regime for at least 8 weeks. The median TTP was 7.1 months (1.7–19.9) and OS was 10.2 months (2.1–20.5). Hand-Foot-Skin reaction (73%), diarrhea (69%) and neutropenia (63%) were the most commonly encountered toxicities,