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TROPISETRON (TRO) VS. ONDANSETRON (OND) IN PROPHYLAXIS OF CHEMOTHERAPY-INDUCED EMESIS (CIE)

Riess H[1], Drechsler S[2], Evers C[1], Faerber L[2]
1: University Hospital R.-Virchow Berlin, 2: Sandoz AG Nuremberg

TRO and OND are both highly selective $5HT_3$-antagonists developed for prophylaxis of CIE. In an open randomised pilot study we compared the efficacy of the two compounds in patients under highly emetogenic chemotherapy (cisplatin ≥ 75 mg/m² or carboplatin ≥ 300 mg/m² on day 1). Patients were randomised to receive either TRO 5 mg or OND 8 mg i.v. on day 1 before start of chemotherapy. Treatment was continued on day 2 - 5 with TRO 5 mg orally o.a.d. or OND 8 mg orally b.i.d.
25 patients (20 males, 5 females, age 53 ± 7.1 years) were entered into the trial, 13 were randomised to receive TRO and 12 to receive OND.
In each treatment group 8 patients had total response (no nausea, no emesis) on day 1. Efficacy assessment by patients and physicians and tolerability assessment by patients were comparable for both groups. Physicians judged tolerability significantly better for the TRO group. Recruition is ongoing, further data will be presented.
Conclusion: First results of an open pilot study comparing TRO and OND in prophylaxis of CIE show comparable efficacy data for the two compounds. For defintive conclusions regarding efficacy and tolerability the data of large double-blind trials will be needed.

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OPTIMAL TREATMENT WITH TROPISETRON (TRO) IN ACUTE AND DELAYED CHEMOTHERAPY-INDUCED EMESIS (CIE)

Bruntsch U[1], Drechsler S[2], Seeber S, Gosse H, Ukena D, Faerber L
1: 5. Med. Klinik, Nuremberg, Germany, 2: Sandoz AG Nuremberg

The development of $5HT_3$-antagonists for prophylaxis of CIE led to a significant increase in control of acute vomiting and nausea on day 1 of chemotherapy. Confirmatory analysis of clinical trials was usually restricted to these acute symptoms. Delayed CIE still cannot be prevented sufficiently by any antiemetic in monotherapy and there is a lack of trials focussing on this issue. In order to assess the optimal treatment with the $5HT_3$-antagonist TRO and its combinations in acute and delayed emesis, we perform a randomised multicenter study comparing 3 different TRO containing treatment schedules:

1) TRO monotherapy: 1 x 5 mg i.v. during chemotherapy, 1 x 10 mg p.o. on 2 days after chemotherapy (2DAC)
2) TRO (schedule as above) + dexamethasone (1 x 20 mg i.v. on day 1 and 2, 1 x 4 mg i.v. or p.o. until 2DAC)
3) TRO + low dose metoclopramide: 20 mg i.v. + 2 x 10 mg p.o. during chemotherapy, 3 x 10 mg on 2DAC

Patients who fail to their assigned treatment may receive a combination of the three compounds in the next course. Main endpoints are nausea and vomiting during the total therapy. Data of ≥ 120 pts will be presented.

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LOW DOSE IMIPENEM IN THE TREATMENT OF FEBRILE NEUTROPENIA.

MD Green, MA Rosenthal, B Cohen, A Roberts, RL Basser.
Department of Medical Oncology, The Royal Melbourne Hospital, Victoria 3050, Australia.

Early institution of empiric antibiotics reduces the mortality associated with febrile neutropenia (FN). We performed a study of Imipenem monotherapy in a dose lower than previously recommended for FN in an attempt to reduce treatment cost and toxicity without compromising efficacy. Patients received intravenous Imipenem 500mg tds for 48 hrs followed by 250mg tds until resolution of fever, neutropaenia and signs of infection. Thirty-three patients with 42 FN episodes were eligible for response and toxicity assessment. The diseases included leukaemias, lymphomas and solid tumours. The median days of fever, neutropaenia ($<500 \times 10^6$/L), Imipenem therapy and hospitalisation were; 2 days (range 1-15), 3 days (range 1-16), 6 days (range 4-19) and 7 days (range 4-49) respectively. In 33 episodes of FN (79%), Imipenem monotherapy was considered successful whilst additional antibiotics were required in the remaining 9 episodes of FN because of ongoing fever. Four of these episodes of fever were eventually deemed to have been tumour-related. Possible toxicity was seen in only one patient in the form of a mild rash. In conclusion, lower than recommended doses of Imipenem monotherapy for FN appears efficacious with less toxicity and substantially reduces drug costs.

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GRANISETRON AS ANTI-EMETIC IN HEMI-BODY IRRADIATION INDUCED NAUSEA AND VOMITING.

AS Alberts, CJ Louw, AJ van Zyl

Department of Radiotherapy
H.F. Verwoerd Hospital and University of Pretoria
Pretoria
South Africa

Hemibody radiotherapy often causes severe vomiting. A single blind study was done to compare the efficacy and safety of intravenous (IV) Granisetron (G) with IV Metoclopramide (M) plus Dexamethasone (D) in the prophylaxis and control of hemibody radiotherapy induced nausea and vomiting. 38 Patients with malignant disease were treated. UHBI was more emetogenic than LHBI. Nausea was predominantly mild to moderate in the majority of patients. 11 of the 22 patients receiving UHBI, vomited during the first 24 hour period. 68,8% of patients receiving G (UHBI) did not vomit where as all the patients receiving M plus D, vomited (p 0,04). Granisetron was more effective than M plus D in the prophylaxis and control of upper hemibody irradiation induced nausea and vomiting.

Photodynamic Therapy

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LONG SURVIVAL-RATE IN PATIENTS WITH ESOPHAGUS CANCER TREATED WITH PDT

L.Corti,L.Norberto,S.Belfontali,M.Schaffer*,C.Boso
F.Cardin,F.Calzavara,E.Dühmke*

University of Padua, Italy
*University of Göttingen, Germany

65 patients with esophageal cancer have been treated with PDT, in alternative to surgical resection, which was controindicated due to concomitance of other pathology such as liver cirrosis,cardiopolmonary failure,multiple malignancies, or poor general conditions. The Patients distribution was as following: 41 superficial cancer (in situ and Stage I),14 Stage II,6 Stage III and IV,4 cases of anastomo-recurrence after esophagectomy. PDT treatment was used alone or combined with other methods such as YAG-lasertherapy, Radiotherapy etc. No significant complications related to treatment were observed.
CONCLUSIONS: Photodynamic-therapy (PDT), has shown to be a valid treatment alternative for inoperable patients,especially with low stage esophagus cancer, prolonging survival-rate in a significant manner.

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PHOTODYNAMIC THERAPY (PDT) IN AIDS RELATED CUTANEOUS KAPOSI'S SARCOMA (KS). **Hebeda KM, Bakker PJM, Huising MT, Meulen FW van der, Hulsebosch HJ, Gemert MJC van, Reiss P, Veenhof CHN. Academic Medical Centre, Amsterdam, The Netherlands.**

Introduction: The aim of this study was to evaluate the role of PDT in the local treatment of KS. The objectives were to determine response rate, duration of response, side-effects and cosmetic result. Patients: All patients (pts) were homosexual males. Previous local treatment of KS, earlier than 4 weeks before the start of the study, and concurrent zidovudine treatment were allowed. The pts received 2 mg Photofrin®/kg i.v. (provided by Lederle/Cyanamid) 48 hours before laser treatment. An Argon-dye or KTP-dye laser were used. KS were irradiated with a power density of 100-150 mW/cm². Evaluation of response, routine laboratory and immuno-virological parameters (CD4+ and CD8+ and p24 antigen) were determined every 4 weeks. Preliminary results: Five pts received 120 J/cm², group 1, 34 KS, mean diameter 1.2 cm (0.5-3.8 cm), four pts 70 J/cm², group 2, 59 KS, mean diameter 1.3 cm (0.3-3.4 cm) and one pt 50 J/cm², group 3, 11 KS, mean diameter 0.8 cm (0.2-2.0 cm). In 6 pts (group 1 n=5, group 2 n=1) with the longest follow-up until now, the complete response rate was 54% after 3 months. High light doses, however, caused severe local and general side-effects, ranging from severe pain, severe local oedema, temporary systemic temperature rise, blisters of the KS and the surrounding skin, skin necrosis and stiffness of underlying muscles. Longlasting crusts, in many cases of the whole spot, appeared. Some lesions healed with scar formation or hyperpigmentation. The overall cosmetic result was not completely satisfactory. With the now available data no important changes in the general trend of the immunologic parameters were seen. Conclusions: Although PDT gives high response rates, the cosmetic result was somewhat disappointing. Because of the severe side-effects, doses of 70-120 J/cm² cannot be recommended.