Introduction
Chemotherapy options for advanced non-small cell lung cancer include platin+vinorelbine, the latter often administered day 1 and 8 in 3 week series. Practice is that patients have a blood sample taken everytime they come in for chemotherapy. However, there is only limited data on leucopenia at day 8 and the value of blood tests before vinorelbine-alone administrations is unknown.
Objectives
Frequency of leukopenia at day 8.
Methods
One hundred patients who received cisplan+vinorelbine or carboplatin+vinorelbine from 2010 to 2013 were identified in hospital files. Platin+vinorelbine was administered at day 1 and vinorelbine alone on day 8. Results of bloodtests taken day 8 were sought in the central laboratory system. A leucocyte count of 2.5 or more was considered sufficient for vinorelbine administration.
Results
Twenty-eight patients received cisplatin+vinorelbine for a total of 77 treatment series. In none of these, leucopenia was found. Fifty-six patients received carboplatin+vinorelbine for a total of 155 series. In five instances leucopenia was found: two patients had leucocytes of 1.7 in the 3rd series, 1 patient had leucocytes of 2.0 in the 3rd series and two patients had leucocytes of 2.2 in the 2nd series. None had signs of infection.
Conclusions
Leucopenia was found in 2.1 % of 232 day 8 vinorelbine administrations. The low frequency of leucopenia and the absence of related infections indicate that routine measurement of leucocytes before administration of vinorelbine is perhaps not needed. Not having to do blood test on day 8, would lead to fewer visits to the clinic and save valuable time for the patient.

13-15-P

MYELO001 – A NOVEL SMALL MOLECULE FOR THE TREATMENT OF CHEMOTHERAPY-INDUCED MYELOSUPPRESSION

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Introduction
Chemotherapy remains the most frequent treatment option for patients with malignant tumors. Myelosuppression is a dose-limiting or delaying toxicity of mono and polychemotherapies. Most frequent toxic effects are neutropenia and thrombocytopenia which increase the risk of infections and haemorrhagic syndrome. Infections associated with leukopenia often require hospitalization, G-CSFs and antibacterial or antiviral therapy, with mortality rates of 2–10 %.
Objectives
Summary of recent data of Myelo001, Imidazolyl Ethanamide Pentandioic Acid (IEPA), a novel molecule, that demonstrated efficacy in treatment of chemotherapy-induced myelosuppression combined with antiviral properties.
Methods
Cell culture and animal model experiments; open-label controlled clinical trials
Results
In preclinical studies, Myelo001 stimulated differentiation and accelerated post-chemotherapy recovery of bone marrow cellularity and peripheral white blood cell numbers. Myelo001 was safe and well tolerated in preclinical and clinical studies up to 28 and 425 days, respectively. In clinical trials only rare side effect of skin rash (allergic reactions) and hypersensitivity, which resolved after cessation of exposure, were observed. Open-label, non-randomized clinical trials, have demonstrated Myelo001 ‘s efficacy to reduce chemotherapy-induced myelosuppression. At a dose of 100 mg Myelo001 (administered orally once daily starting 5 days prior to the first chemotherapy cycle (CC) until termination of the last CC) significantly reduced grade III/IV toxicity events of neutropenia by about 50 %.
Conclusions
Myelo001 is well tolerated and has a good safety profile. It is a promising novel molecule that warrants further investigation. Myelo001 is planned to enter clinical development in Europe in 2015 to confirm its efficacy in a randomized, double-blind, placebo-control study.

Figure 1: Nonclinical results in CD1 mice:
Leucocyte count (10^9/L) absolute change from baseline in 5 parallel treatment groups

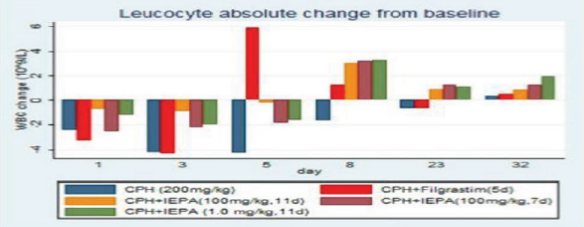
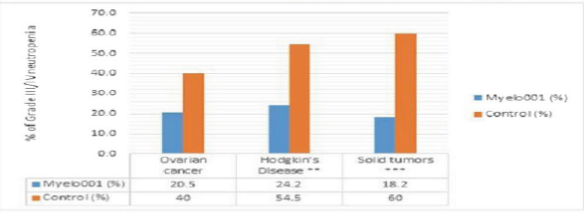


Figure 2: Clinical results in Ovarian cancer, Hodgkin's Disease** and Solid tumors****



*Source: Data on file Myelo Therapeutics GmbH: Study report Myelo001.01.03.0002, Myelo001.01.03.0001, Myelo001.01.03.0034; **The study in Hodgkin's disease was conducted as a sequential design comparing first cycle (No Myelo001) versus second cycle (Myelo001) (intra-patient control). The other two studies had a 2-armed parallel design; ***patients with metastatic solid tumors of various locations: breast cancer 71.4%, ovarian cancer 15.5%, lung cancer 8.8%, prostate cancer 2.4%, gastric cancer 1.2% and tongue cancer 1.2%.

13-16-P

ASSESSING ALTERNATIVE DOSING STRATEGIES FOR GRANULOCYTE-COLONY STIMULATING FACTOR (G-CSF) USE WITH MFOLFOX6 THERAPY FOR TREATMENT OF COLORECTAL CANCER IN A PROSPECTIVE COHORT

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Introduction
Neutropenia is a serious risk factor for treatment delays. Clinical guidelines recommend an average of 11 injections of granulocyte-colony stimulating factor (G-CSF) per cycle of chemotherapy.
Objectives
Few studies support alternative dosing strategies for G-CSF use by cancer type and chemotherapy regimen.
Methods
From 2004 to 2013, 63 colon and 47 rectal cancer patients were recruited and monitored throughout the course of their mFOLFOX6 therapy. G-CSF use was determined by a clinical pharmacist and tracked every week to ensure patients received an adequate number of injections and were compliant with each cycle. Occurrence of neutropenia and febrile neutropenia were compared between patients receiving four and five injections per cycle.