Prospective randomized trial of Palifermin (Keratinocyte growth factor) versus best supportive care measures (BSC) for the prevention or decrease of oral mucositis (OM) in lymphoma patients receiving high-dose BEAM- (BCNU, Etoposide, Ara-C, Melphalan) conditioning and autologous stem-cell transplantation (ASCT)

Prospektive randomisierte Vergleichsstudie zum Einsatz von Palifermin (Keratinozytenwachstumsfaktor) versus „best supportive care"-Maßnahmen (BSC) zur Prävention oder Verminderung einer oralen Mukositis (OM) nach Hochdosischemotherapie mit BEAM- (BCNU, Etoposid, Ara-C, Melphalan) Konditionierung und autologer peripherer Blutstammzelltransplantation bei Patienten mit malignen Lymphomen

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Introduction: Palifermin has been demonstrated to significantly prevent or lessen the extend and duration of ulcerative (WHO grade [G] 2-4) and severe mucositis (G3+4), albeit after myeloablative TBI-/cyclophosphamide-containing conditioning. Its role in today commonly used conditioning regimens such as BEAM has not been determined. This is especially of interest since the extend of BEAM-induced OM varies greatly as shown by our group (Strobel et al., 2007). We therefore performed this prospective randomized trial of palifermin vs. BSC in BEAM-conditioned consecutive patients to assess the incidence, severity and duration of OM. Secondary end-points were differences in supportive care measures, progression-free- (PFS), overall-survival (OS) and risk factors for OM.
Patients and Methods: The intention-to-treat (ITT) group included 73 non-Hodgkin's- or Hodgkin's-lymphoma-patients, randomly assigned to the study- (n=37) or control-arm (n=36). The per-protocol (PP) group included 22 patients who received 60µg/kg Palifermin i.v. for 3 consecutive days before and after BEAM and 32 patients receiving BSC measures. OM was assessed daily until hospital discharge. Duration of opioid-use (OU), total parenteral nutrition (TPN), febrile neutropenia (FN), hospital stay (HS) were also meticulously documented.
Results: BEAM-doses between the palifermin vs. BSC groups were not different. Baseline characteristics (remission status, age and reinfused CD34+-cells) were well balanced. In the palifermin vs. BSC-group of the ITT-group, ulcerative and severe OM incidences were lower with 40% vs. 56%, and 23% vs. 31%, and the median OM-duration was shorter with 5 vs. 6 days, albeit these differences did not reach significance (p=0.59, 0.23, 0.18, respectively). In the PP-group, greater differences were observed with ulcerative OM-rates in the palifermin vs. BSC-group of 36% vs. 63% (p=0.23) and severe OM-rates of 18% vs. 34% (p=0.0958), respectively. Here, median OM-durations were significantly different with 3.5 days in the palifermin- vs. 7 days in the BSC-group (p=0.0165). OU, TPN, FN, HS and engraftment were reduced with palifermin in the ITT- and PP-groups, albeit without statistical significance. Median PFS was not reached (nr) vs. 41 months (p=0.46) in the palifermin vs. BSC-group, respectively. Median OS was nr in both groups (p=0.89).
Conclusion: Palifermin reduces the duration of OM after high-dose BEAM and ASCT. Risk factor analyses will be presented at the meeting.