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Megadoses of autologous Tissue Repair Cells (TRC) in the treatment of Ischemia induced chronic issue ulcers of diabetic foot patients without option of revascularisation ? preliminary results from Bad Oeynhausen

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Diabetic foot syndrome (DFS) appears as a concomitant illness of diabetes mellitus. Diabetes is one of the main causes of non-traumatic amputation in Germany due to severe peripheral arterial occlusive disease (PAOD) with chronic critical limb ischemia (CLI) being the most abundant problem. Ulceration occurs as failure of the microcirculation and progressive occlusion of the larger blood vessels exacerbates pre-existing microvascular abnormalities.

For the first time megadoses of pluripotent stem and progenitor cells - Tissue Repair Cells (TRCs) - are used in the treatment of diabetic ulcers to induce revascularisation of the affected limb and to enhance local perfusion. As a concomitant result wound healing, which is highly dependent on perfusion, should occur and lead to preservation of the limb. DFS patients with chronic limb ischemia and without the option of surgical or interventional revascularisation are being recruited and randomized to either the transplant group or the control group within this clinical trial. Approximately 40 ml of bone marrow is harvested from the iliac crest, followed by

preparation and culture of mononuclear cells. Application sites of the enriched mesenchymal bone marrow cells (BMCs) or Tissue Repair Cells (TRCs) are intramuscular (i.m.) into the gastrocnemius of the affected limb or intra-arterial (i.a.) into the femoral artery. Of the 26 patients have been enrolled in the study. 10 patients have completed the 12 month follow-up, 2 patients were immediately dropped from the study due to low bone marrow quality, 1 patient from the control group and 1 patient from the BMC i.a. left the study to receive major amputations, 1 patient withdrew his consent and the other 11 patients are still in the follow-up period. To measure the therapeutic effects of the various treatment arms patients were evaluated for ABI, TcpO₂, and reactive hyperemia (Laser Doppler and BOLD). Patients also underwent imaging with angiographic methods..All patients treated with BMCs or TRCs, independent of application method, showed tendential improvement of microcirculation (reactive hyperemia) in the affected foot as well as complete primary wound healing. No serious adverse events related to the treatment were noted. In

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addition, no calcification of soft tissue has been observed. The transplantation of expanded autologous bone marrow stem cells as well as mesenchymal bone marrow cells in diabetic patients with critical limb ischemia induced chronic tissue ulcers proved to be safe and shows tendential improvement of microcirculation and complete wound healing.

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