Mesenchymal Stem Cells (MSCs) are pluripotent cells that have potent immunosuppressive effects on T and B cells in vitro and in animal models of chronic inflammation. Encouraging results have been obtained in patients with steroid resistant, acute and severe graft versus host disease (GvHD), including GvHD of the gut.

The objective of this study was to determine the safety and feasibility of autologous bone marrow derived MSC therapy in patients with refractory CD.

**Methods:** After informed consent, 7 adult patients (5 females/2 males, median age 34 years) with refractory, moderate to severe CD with a Crohn’s disease Activity Index (CDAI) score of at least 220 underwent bone marrow aspiration (100 ml) under local anesthesia. Mononuclear cells were isolated by density gradient centrifugation and plated in culture medium containing 10% Fetal Calf Serum (FCS). MSCs were expanded in culture until passage 1–3. To date, five patients received 2 doses of 1–2 million cells/kg bodyweight, intravenously, 7 days apart. Primary outcomes were feasibility and safety of autologous MSC expansion and infusion. Secondary outcomes were changes in the CDAI score and Crohn’s disease Endoscopic Index of Severity (CDEIS).

**Results:** MSC from CD patients showed the typical spindle-shaped morphology and similar growth potential and yield comparable to MSCs from healthy donors (n = 7). The initial median CDAI score in the first five patients treated was 334 (range 254–350). MSC infusion was successful and without side effects, with exception of a mild allergic reaction to the cryopreservant dimethyl sulfoxide (DMSO) in one patient. One patient dropped out of the study at week 4 because of severe relapse necessitating surgery. The other four treated patients showed an average decrease in median CDAI score of 107 points 6 weeks post transplantation. Endoscopic improvement was seen in two patients with extensive CD localized in the colon whereas no significant improvement was seen in two patients with ileal CD.

**Conclusion:** Autologous bone marrow derived Mesenchymal Stem Cell therapy seems to be feasible and safe in the treatment of refractory Crohn’s disease.

**P092 Efficacy and safety of methotrexate therapy in inflammatory bowel disease. The Madrid experience**

Y. Gonzalez-Lama*. La Princesa and Getafe Hospitals, Madrid, Spain

**Introduction:** There is enough evidence of the usefulness of methotrexate (MTX) in inflammatory bowel disease (IBD), but at present its role is secondary due to a lack of experience in its use and a supposed unfavourable profile of adverse effects.

**Aims and Methods:** To describe a retrospective series of IBD patients treated with MTX in several hospitals from the Madrid area (Spain).

**Results:** 77 patients were included: 80% Crohn’s disease (CD), 37% male, mean age 41 years. Patients characteristics according to Montreal Classification were, for CD: 5%A1, 75%A2, 19%A3; 39%L1, 12%L2, 42%L3, 7%L4; 54%B1, 19%B2, 26%B3, 21%; and for ulcerative colitis (UC): 43%E2, 57%E3. MTX was prescribed due to steroid-dependency in 94% of patients, and due to steroid-resistance in the remaining. MTX was initiated at a mean dose of 21 mg/wk (range 13–28) mg/wk; 82% of the patients responded (28% clinical remission). 88% of the patients followed maintenance treatment, at a mean dose of 15 mg/wk (range 8–25) for a mean of 17 months (range 1–108), either oral (33%), intramuscular (22%) or subcutaneous (44%). In this period, 39% of the patients lost response, in a mean of 57 weeks after starting MTX; this forced a treatment change in most cases, except for 5 patients whose MTX dose was increased (3 responded). No statistically significant differences were found in response rates regarding the type of disease (UC/CD), way of administration, or Montreal classification. Mean MTX cumulative dose through the follow up was 1,108 mg (range 25–6,480). Hepatotoxicity was detected in 10 patients (13%), but ultrasonographic signs of chronic liver disease were found only in 1 case. There were 4 cases of myelotoxicity (5%), 1 (1.5%) of enterocolitis, alopeca, estomatitis and cutaneous rash, and 10 (13%) of gastrointestinal symptoms. No case of neumonitis was detected. Withdrawal of MTX was necessary due to adverse events in 4 (5%) patients. Risk of hepatotoxicity was not related with the MTX cumulative dose. Hepatic elastography (FibroScan) was performed in 47 patients. In patients with hepatotoxicity, mean stiffness was 6.2 kPa (range 3.5–15.3); normal or mild fibrosis (F0/F1) was found in 86%, and advanced in 1 case. No differences could be found in stiffness or stage of fibrosis regarding the presence of MTX induced hepatotoxicity.

**Conclusions:** MTX is useful in inducing remission in IBD, although its efficacy diminishes frequently through follow up. This treatment may be considered relatively safe, with a low rate of adverse events. MTX induced hepatotoxicity is rare, and very seldom means a clinically relevant issue.

**P093 Cyclophosphamide therapy for inflammatory bowel disease**

A. Nagy*, A. Zöld, M. Zeher, Z. Barta. IBD Workgroup, Debrecen, Hungary

**Aim:** To demonstrate the efficacy of intravenous cyclophosphamide therapy for inflammatory bowel disease.

**Methods:** We included in our cohort 32 patients with steroid refractory IBD, 15 with Crohn disease and 17 with ulcerative colitis. They received 6 cycles of intravenous cyclophosphamide (800 mg per month) under clinical circumstances.

**Results:** We experienced disease activity decreasing after the second/third pulse cyclophosphamide infusion. Some of the patients entered into remission both from a clinical and laboratory points. We only noticed just once side effect of the...