**AMINO ACID ORAL REHYDRATION SOLUTION**

Entera is an amino acid-based, glucose-free medical food/beverage with electrolytes. It comprises of 5 amino acids (Valine, Aspartic Acid, Serine, Threonine, Tyrosine) selected to rebuild villi, protect the GI tract and promote hydration. I. These nutrients facilitate retention of the absorbing capacity of the small intestine by rebuilding the vili and reduce antigenic translocation by tightening the mucosal barrier. In a study of irradiated mice, entera improved survival and improved body weight following irradiation. On electron microscopy of the ileum, there was loss of cell-to-cell contact after irradiation, which was restored after the introduction of entera.**

**INTRODUCTION**

The alkylation agent, melphalan, remains the mainstay of conditioning for autologous hematopoietic stem cell transplantation (HSCT) in multiple myeloma (MM) and non-Hodgkin lymphoma (NHL) patients. The mucosal sequelae of Melphalan and the subsequent enteritis are similar to those induced by total body irradiation, with approximately 40% of patients experiencing CTCAE grade 2 or higher diarrhea following conditioning regimens containing Melphalan. This study was to assess the effectiveness of entera in reducing grade ≥2 diarrhea associated with high dose Melphalan chemotherapy.**

**METHODS**

The trial was designed as a Phase 2, multi-center, double blinded, 2-arm randomized study. 114 MM or NHL patients were enrolled between October 2016 and October 2017. Patients were randomized 1:1 to receive either two 8oz bottles of entera or Placebo starting on the day of admission through Day +14. GI toxicity was scored by the CTCAE 4.0 system from admission through Day +14. Compliance was arbitrarily set at consumption of 2 bottles daily for 11+ days.

**Schema:**

- **Treatment:**
  - ARM A: Entera® (5% and standard of care)
  - ARM B: Placebo (5% and standard of care)

- **Comparison:**
  - NHL/MM, Hodgkin/Lymphoma
  - Placebo vs. entera®

**DEMOGRAPHIC/RESULTS**

Compliance overall was much lower than anticipated; with no MM patients achieving compliance compared to 34.2% in the NHL group. Compliance in NHL patients was 31.6% in the entera group versus 36.8% in the placebo group.

**CONCLUSIONS**

- **11 Days of two 8oz bottles of liquid is a difficult task during ASCT, especially for MM with nausea, altered taste and poor appetite.**
- **For those NHL patients, compliant per protocol (who consumed ≥11 days), entera significantly reduced diarrhea.**
- **At ≥7 days of treatment there was also a signal for effect.**
- **The use of entera to prevent high dose chemotherapy associated diarrhea should be explored further in populations capable of reasonable oral intake.**

**REFERENCES**

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