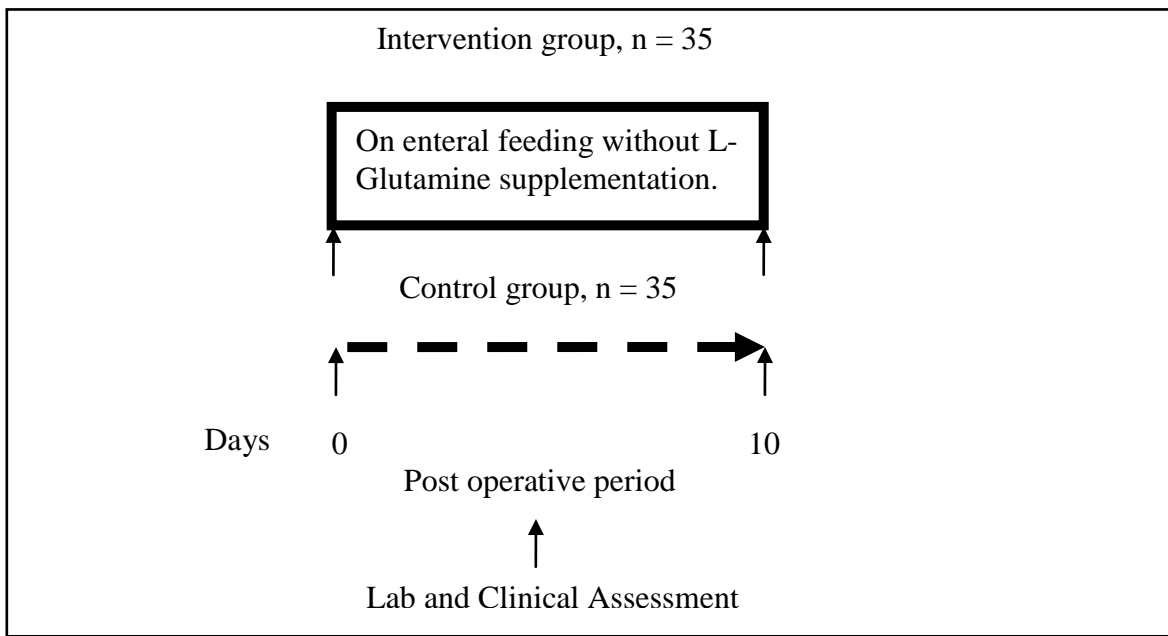


6. Intervention:

Subjects in the intervention group after surgery will receive L-Glutamine Supplementation with isocaloric/ isonitrogenous diet via enteral route. Subjects will receive approximately 10gms of glutamine /day with isonitrogenous diet containing 2500k.cal/ day for 10 days in the postoperative period. Those in the control group will receive isonitrogenous diet only containing 2500k.cal/ day. Both groups will receive concomitant medications as prescribed by their surgeons during their study period.

Data analysis: Data will be analyzed using SPSS 16 for windows. Data will be analyzed for homogeneity and normal distribution and appropriate inferential statistics will be applied. Bivariate relationships between outcome variables will be determined using correlation statistics.

Figure 1: Design of Study



7. Scope of the study:

The main objective of the study is to evaluate the effect L-Glutamine enteral supplementation on antioxidant status, nutritional status, systemic inflammatory response and postoperative outcomes in patients undergoing surgery for Head and Neck cancers or Upper GI cancers. This study will provide information on the importance of glutamine supplementation or nutrition in cancer patients on enteral feeding in the postoperative period. This study will evaluate if nutritional interventions improve postoperative outcomes and reduce systemic inflammatory response that affect survival and overall treatment response in these patients. This study will provide preliminary data to carry out larger randomized controlled trials in this area.

8. Utility (usefulness) of the study:

It has been well documented that poor nutritional status is related to less treatment compliance, poorer treatment response and reduction in overall survival in cancer patients. Improving this aspect would therefore improve the treatment response and survival and also affect one's functional quality of life. If enteral glutamine supplementation is found to improve post-operative outcomes, nutritional status and reduce systemic inflammatory response, it can serve as an adjuvant therapy to conventional treatment in patients with head and neck and upper GI malignancies undergoing surgery for tumor resection. Further studies can be conducted to validate the effects of glutamine supplementation as a chemopotentiator.

9. Limitations (restriction) of the study:

This study involves a small cohort of subjects and hence would be a pilot study. Secondly the results of the study can be confounded due to the heterogeneity in stages of cancer. However we hope to minimize these confounding effects by controlling for stage in the statistical analysis. The results of the study is only limited to patients with upper GI malignancies and Head and Neck cancers on enteral feeds and cannot be generalizable to all cancers and situations.

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The present study examined the antioxidant defense of glutamine on plasma and liver antioxidant status in broilers under PHS with respect to changes in the levels of lipid peroxidation marker malondialdehyde (MDA), total antioxidant status (TAS) and the activities of anti peroxidative enzymes [superoxide dismutase (SOD) and glutathione dependent antioxidant enzymes glutathione peroxidase (GPX)] in the plasma and liver tissue. Learn more about Glutamine health benefits, uses, side effects, effectiveness, safety, precautions, and warnings.
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Glutamine, or L-glutamine, is an amino acid derived from glutamic acid [1]. Glutamine is the most abundant free amino acid in the body and commonly known as a nonessential amino acid. Glutamine is present in the plasma at levels around 0.6mM and in the intracellular space at levels around 2 and 20mM.
How to cite this article: Daniyah A A, Mahmoud M A. Effect of Glutamine Supplementation in Patients with Inflammatory Bowel Diseases. *Nutri Food Sci Int J.* 2016; 1(5): 555574. DOI: 10.19080/NFSIJ.2016.01.555574.