|  |  |
| --- | --- |
| Study Title | Post-Operative Extended Enteral Nutrition in Patients with Oesophageal Cancer requiring Oesophagectomy - A pilot study |
| Study name |  |
| Study AIm/  objectives | The aim of this study would be to assess the nutritional impact of providing enteral feeding for patients over the first 12 weeks post operatively following major upper gastrointestinal surgery. |
| Study design | Randomised Controlled Trial |
| study subjects | Patients having curative oesophagectomy |
| Inclusion criteria | * Adult patients * Patients having had curative oesophagectomy * Patients being discharged to home with jejunostomy feeding tube in situ * Ability to provide written consent |
| Exclusion criteria | * Patients who experience tube failure * Inability to attend appointments at JHH at 3 and 6 months post op. |
| outcome parameters |  |
| Primary | Weight Change |
| Secondary | SGA  Diet Intake data via 24 hr recall- Total Energy, Macronutrient intake, Targeted Micronutrients  Biochemical markers – CRP, EUC, CMP, Fe- studies, Micronutrients (Zinc, Selenium, B12, folate),  Sarcopenia assessed via psoas cross-sectional area measurement  Quality of Life Using (QLQ-C30 Core Questionnaire and Oesophageal Module)  Assessment of Body Composition (Skeletal Muscle Index)  Hand-grip  Walk test |
|  |  |
| safety AND TOLERANCE parameters | Gastro symptoms and tolerance |
| OTHER PARAMETERS | Compliance (based on recording number of bottles used/unused) |
| Study groups | All patients will have jejunal feeding post-operatively in hospital. All patients will have baseline data collected in the first week post operatively.  Patients will be provided with an enteral feeding pump, and education on enteral feeding and caring for a jejunal feeding tube. They will be asked to run continue enteral feeds overnight providing (20Cal/kg) overnight via their existing jejunal feeding tube. Total amount of time on enteral feeds will be approx. 10-12 hours.  On discharge (approx. 2 weeks post -operative), all patients will be provided with standardised education on a high energy, high protein diet and appropriate textures (puree then moving to soft).    All patients will be provided with contact details for the dietitian in case of any problems with the feeds. The first review will occur at the time of the surgical follow up which is 4 week post discharge (approx. Week 6 post-operative). Those randomised to the control arm will have feeds ceased at 6 weeks.  Enteral provision of nutrition support in the intervention arm will be ceased at Week 12 post op and the high energy, high protein diet and small frequent eating education will be reiterated. Oral nutrition support will be provided to patients as required.  A 3 month face-to-face review will be arranged, and 12 week data collection will take place at this time. Further follow-up will be arranged depending on need.  Patients will be seen again at week 26 to review progress. |
| study regimen | **Control Group**: Overnight continuous enteral feeding through a jejunal feeding tube that provides 20kcals/kg for 6 weeks post operatively.  **Intervention Group:** Overnight continuous enteral feeding through a jejunal feeding tube that provides 20kcals/kg for 12 weeks post operatively. |
| Study period | Duration of the study for each patient will be approximately 6 months.  At the JHH there are approximately 15 patients per year. We aim to collect data on approximately 30-40 patients and as a result the study may take 2-3 years to complete. |
| Statistical Analysis | All normally distributed data will be presented as mean +/- SD. Data will be compared between the control and intervention groups at week 12 and week 26. For continuous data (eg. Percentage weight change and skeletal muscle index), mean difference between these two groups will be assessed using a t-test for normally distributed data and Mann Whitney test will be performed if data is not normally distributed. Chi square tests for associations between variables and groups will be conducted if data is categorical (SGA categories). Regression analysis will be conducted to determine the impact of factors such as age, gender and BMI on the relationship between the intervention and percentage weight change. |