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| Study Title | Jejunal verses oral nutrition for one month post hospital discharge after major upper gastrointestinal surgery – a multicentre RCT  |
| Study name | Post-discharge JEJ feeding study |
| Study AIm/objectives | The aims of this study would be to assess the impact of providing 900cal from enteral feeding verses oral supplements within the first month of discharge, for patients following major upper gastrointestinal surgery. |
| Study design | A multi-centre randomised controlled trial |
| study subjects | Patients having curative oesophagectomy or total gastrectomy  |
| Inclusion criteria | * Patients having had curative oesophagectomy or total gastrectomy
* Patients being discharged to home
* Ability to provide written consent
* Sites that routinely place jejunal feeding tubes for post-op feeding in this patient group
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| Exclusion criteria | * Patients having non-curative surgery.
* Patients discharged to another facility other than home
* Patients with complications requiring enteral feeding at home, unable to be randomised.
* Patients with limited English or mental capacity to provide consent
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| outcome parameters |  |
| Primary | Weight Change |
| Secondary  | PG-SGA, EORTC-QOL, Grip Strength/TSF, Total Calorie and Protein intake |
| Exploratory | Compliance, Complications, Gastro symptoms, readmissions |
| safety AND TOLERANCE parameters  | Complications (measured by a standardised checklist) and Gastro Symptom measures (recorded at review and also as a part of the Quality of Life Questionnaire) |
| OTHER PARAMETERS | Compliance (based on recording number of bottles used/unused) |
| Study groups | All patients will have jejunal feeding post-operatively in hospital. Prior to discharge patients will be randomised into a control or intervention group. All patients will have baseline data collected at time of discharge from hospital.All patients will be provided with standardised education on a high energy, high protein diet and small frequent eating. The control group (n=25-30) will also be asked to consume 3 × Fortisip multifibre per day for 30 days post-discharge from hospital. Patients recruited to the intervention group (n=25-30) will be provided with an infinity enteral feeding pump, and education on enteral feeding and caring for a jejunal feeding tube. They will be asked to run 60ml/hr of Nutrison Energy Multifibre overnight via continuous enteral feeding through a jejunal feeding tube. Total amount of time on enteral feeds will be 10 hours. 50ml water flush before and after feeds. All patients will have weekly phone review for the first month using a standardised checklist, and a face-to-face review at one month. One month data will be collected at this review appointment (either by phone or face-to-face). Both oral and enteral provision of nutrition support will be ceased at one month, 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, and enteral nutrition will only continue if deemed necessary. A 3 month face-to-face or phone review will be arranged, and 3 month data collection will take place at this time. Further follow-up will be arranged depending on need.  |
| study product regimen | **Control group:** patients will receive 3 × Fortisip +/- multifibre per day for 30 days post-discharge from hospital**Intervention group:** patients will receive 600ml Nutrison Energy +/-Multifibre overnight via continuous enteral feeding through a jejunal/NJ feeding tube.  |
| Study period | Duration of the study for each patient from randomisation to completion of study will be approximately 3 months. It is expected with a multicentre study, recruiting 50-60 patients will take 1 year.   |
| Target dates:Final protocolFirst subject RECRUITEDFinal results |  |
| End May 2015 (and ethics by August 2015)September 2015 |
| N=50-60 |
| September 2016 |
| POWER CALculation | For a **one-sided** statistical significant (α = 0.05 and 80% power) with a 2kg difference between groups (=/- 5.5 SD)N=47For a **two-sided** statistical significant (α = 0.05 and 80% power) with a 2kg difference between groups (=/- 5.5 SD)N=60 |
| Statistical Analysis | Basic comparison statistics (t-test and ANOVA)Correlations (persons rho)  |
| SITES AND PRIMARY INVESTIGATORS | CHIEF INVESTIGATOR: Dr Sharon CareyCHIEF INVESTIGATOR: Dr Charbel SandroussiASSOCIATE INVESTIGATOR: Suzie FerriePRIMARY INVESTIGATOR FOR ROYAL PRINCE ALFRED HOSPITAL: Michelle HarrisonPRIMARY INVESTIGATOR FOR PRINCE OF WALES HOSPITAL: Suzie DanielsPRIMARY INVESTIGATOR FOR NEPEAN HOSPITAL: Trang SorianoPRIMARY INVESTIGATOR FOR LIVERPOOL HOSPITAL: Ruth VoPRIMARY INVESTIGATOR FOR THE MATER HOSPITAL: Jocelyn KingPRIMARY INVESTIGATOR FOR CONCORD REPATRIATION GENERAL HOSPITAL: Eleanor QuinnPRIMARY INVESTIGATOR FOR THE ALFRED HOSPITAL: Lisa MurnanePRIMARY INVESTIGATOR FOR ST GEORGE HOSPITAL: Lauren ReecePRIMARY INVESTIGATOR FOR WESTMEAD HOSPITAL: Elizabeth ParkerPRIMARY INVESTIGATOR FOR ROYAL NORTH SHORE HOSPITAL: Murielle Ryan |