Fakultät für Medizin

Klinikum rechts der Isar Technische Universität München

# PERCOG

Parenteral nutrition during neoadjuvant chemotherapy for patients with non-metastatic gastric or gastroesophageal cancer to reduce postoperative morbidity

Phase III Trial

**Test products:**
Nutriflex Omega plus BBRaun®
Nutriflex Omega special BBraun®
Nutriflex lipid plus BBraun®
Clinimix BAXTER®
Aminomix Fresenius Kabi®

**Study Code:** PERCOG

**EudraCT Number:** 2015-005219-34

**First Patient First Visit:** 24.05.2019 **– Last Patient Last Visit:** 28.10.2021

Termination of Clinical Trial: 28.10.2021 (LPLV)

**Sponsor**
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**Version:** Final 1.0. 28.10.2022

# Synopsis

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| 1. | **Sponsor:**<br>Technische Universität München (TUM), Fakultät für Medizin<br>Ismaninger Strasse 22, D- 81675 München, Germany<br>**Sponsor Delegated Person (SDP):**<br>Prof. Dr. med. Daniel Reim |
| 2. | **Name of Finished Product:** Nutriflex Omega plus BBRaun®, Nutriflex Omega special BBraun®, Nutriflex lipid plus BBraun®, Clinimix BAXTER®, Aminomix Fresenius Kabi® |
| 3. | **Name of Active Ingredient:** ATC Code: B05BA10 |
| 4. | **Individual Study Table:** (only required for submissions) n.a. |
| 5. | **Study Title:** Parenteral nutrition during neoadjuvant chemotherapy for patients with non-metastatic gastric or gastroesophageal cancer to reduce postoperative morbidity |
| | **Study Design:** Randomized controlled trial |
| | **Study (Protocol) Code Number:** DRKS00009451 |
| | **Eudra-CT Number: 2015-005219-34** |
| 6. | **Investigator(s):**<br>#1 Prof. Dr. Daniel Reim, Klinikum Rechts der Isar der TU München (LKP)<br>#2 PD Dr. Markus Albertsmaier, Ludwig-Maximilian-Universität, Klinikum Großhadern<br>#3 Prof. Dr. Jakob Izbicki, Klinik u. Poliklinik für Allg.-, Viszeral-, Thoraxchirurgie, UKE Hamburg<br>#4 Prof. Dr. André Mihaljevic, Klinik für Allg.-, Viszeral-, Transplantationschirurgie, Universitätsklinikum Heidelberg<br>#5 Prof. Dr. Ines Gockel, Klinik und Poliklinik für Viszeral-, Transplantations-, Thorax- u. Gefäßchirurgie, Universitätsklinikum Leipzig<br>#6 Prof. Dr. Peter Grimminger, Allgemein-, Viszeral und Transplantationschirurgie, Universitätsmedizin Mainz |
| 7. | **Participating Study Centres :**<br>#1 Klinikum rechts der Isar an der<br>Technische Universität München<br>Klinik und Poliklinik für Chirurgie<br>Ismaninger Straße 22<br>D- 81675 München, Germany<br><br>#2 Klinikum der Universität München<br>Klinik für Allgemein-, Viszeral-, Transplantations- und Gefäßchirurgie<br>Marchioninistr. 15<br>D-81377 München<br><br>#3 Universitätsklinikum Hamburg-Eppendorf (UKE)<br>Klinik u. Poliklinik für Allg.-, Viszeral-, Thoraxchirurgie |

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| | Martinistr. 52,<br>20246 Hamburg<br>Keine Rekrutierung<br><br>#4 Universitätsklinikum Heidelberg<br>Klinik für Allg.-, Viszeral-, Transplantationschirurgie<br>Im Neuenheimer Feld 110,<br>69120 Heidelberg<br>Keine Rekrutierung<br><br>#5 Universitätsklinikum Leipzig AÖR<br>Klinik und Poliklinik für Viszeral-, Transplantations-, Thorax- u. Gefäßchirurgie<br>Liebigstr. 20,<br>04103 Leipzig<br>Keine Rekrutierung<br><br>#6 Universitätsmedizin Mainz<br>Allgemein-, Viszeral und Transplantationschirurgie<br>Langenbeckstraße 1,<br>55131 Mainz<br>Keine Rekrutierung |
| **8.** | **Publication:** not published |
| **9.** | **Study period:**<br>First patient first visit (FPFV): 24.05.2019; Last patient out: 28.10.2021<br><br>Due to recruitment problems, the study was terminated early. |
| | **Approvals and Amendments**<br><br>**Approval**: Bundesinstitut für Arzneimittel und Medizinprodukte （BfArM/PEI): 18.04.2017; Ethics Committee (EC): 16.05.2017<br><br>**Amendment 1**:The following major changes were included in AM 1:<br>*Inclusion criteria were extendend to pancreatic and rectal cancer patients requiring neoadjuvant therapy in order to increase recruitment rates. The following trial sites were amenden to increase recruitment: University of Leipzig und University of Mainz. Trial site University of Heidelberg was closed as no patient recruitment was feasible.*<br><br>Approval AM1: BfArM/PEI: 01.04.2021; EC: 01.07.2021, CSP Version 3.0, 26.05.2020 |
| **10.** | **Phase of development**<br>Phase III |
| **11.** | **Objectives:**<br><br>**Primary Objective:** Comprehensive Complication Index on day 30 after oncologic resection |

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| | **Secondary Objectives:**<br>Registration of the complication rate during neoadjuvant chemotherapy according to the Common Terminology Criteria for Adverse Events (CTCAE v4.03).<br>Registration of the complication rate associated with application of parenteral nutrition according to CTCAE v4.03.<br>Registration of the total amount of complications and postoperative morbidity within a postoperative period of 30 days according to the Clavien-Dindo classification and CTCAE v4.03.<br>Registration of Quality of Life according to EORTC QLQ-C30 questionnaire.<br>Development of body weight and BMI<br>Length of hospital stay<br>Length of ICU stay |
| **12.** | **Methodology**<br>Oncologic patients undergoing multimodal therapy (neoadjuvant/perioperative (radio-) chemotherapy for esophageal, gastric, pancreatic or rectal cancer reveal an increased risk of malnutrition which may result in increased postoperative complications. The study aimed to investigate if supportive parenteral nutrition (SPN) during routine multimodal oncologic treatment ahead of surgery reduces postoperative complication rates measured by the Comprehensive Complication Index (CCI). Patients fulfilling inclusion criteria as specified were randomized either to receive daily 600 kcal of SPN via a port-system (interventional group) during the routine multimodal oncologic treatment until surgery or no SPN (control group). Patients recorded their daily calory intake by diaries and Quality of life was assessed according to EORTC-QLQ C30 questionnaires. All procedures, diagnostics and therapies followed clinical routine. Patients were followed after finishing the first half of the respective multimodal treatment regimen, after completion and ahead of surgery. Patients received surgical resection 30-40 days after multimodal treatment completion. Postoperative complications according to the Clavien Dindo classification system were recorded and assessed on postoperative day (pod) 7, at discharge until pod30. |
| **13.** | **Sample size (planned/analysed):**<br>Planned: 150 patients<br>Included / analysed: 15 patients |
| **14.** | **Patient Population (Diagnosis):** *(gem. EU-CTR Vorgabe bitte Altersstruktur nach Geschlecht und Auswertungsgruppen (IIT, PP, SA) differenzieren)*<br>ICD10: C16 - Malignant neoplasm of stomach, C15 – Malignant neoplasm of the esophagus, R64 - Cachexia,<br>Gender: Both, male and female<br>Minimum Age: 18 Years<br>Maximum Age: no maximum age |
| | **Main criteria for inclusion**<br>1.) Histologically proven resectable adenocarcinoma of the stomach or gastroesophageal junction (AEG I-III) staged cT2/cN+ to cT4/cNany without distant metastasis.<br>2.) Age >= 18 years<br>3.) ECOG stage 0-2<br>4.) Nutritional Risk Score (NRS) ≥3<br>5.) Negative proof of pregnancy for potentially childbearing women. |

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| | 6.) Sufficient bone-marrow, liver- and kidney-function according to the attending oncologist´s expert opinion. |
| 15. | **Test product, dose and mode of administration**<br>**Study treatment:** Daily amount of 600 kcal of supportive, parenteral nutrition during preoperative neoadjuvant chemotherapy<br>**Control**: Neoadjuvant chemotherapy without provision of supplemental parenteral nutrition.<br>**Batch-No. (Ch.-B):** not applicable |
| | (Authorisation Number 34134.00.00) |
| 16. | **Duration of administration: Maximum 12 weeks** |
| 17. | **Background therapy: S**tandard of care (no supplementary parenteral nutrition)<br>**Comparator:** None |
| | **Blinding:**<br>Yes, investigator/therapist, assessor, data analyst |
| 18. | **Criteria for evaluation:**<br>**Primary endpoint:**<br>Comprehensive Complication Index on day 30 after oncologic resection<br><br>**Secondary questions:**<br><br>1. Registration of the complication rate during neoadjuvant chemotherapy according to the Common Terminology Criteria for Adverse Events (CTCAE v4.03).<br>2. Registration of the complication rate associated with application of parenteral nutrition according to CTCAE v4.03.<br>3. Registration of the total amount of complications and postoperative morbidity within a postoperative period of 30 days according to the Clavien-Dindo classification and CTCAE v4.03.<br>4. Registration of Quality of Life according to EORTC QLQ-C30 questionnaire.<br>5. Development of body weight and BMI<br>6. Length of hospital stay<br>7. Length of ICU stay |
| | **Efficacy:** Efficacy assessments following endpoint analysis. |
| | **Safety assessments**<br><br>Safety was assessed from the initiation of therapy until 30 days after the last application of the IMP. Safety was assessed according to CTCAE v4.03. AE reporting was exempt in |

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| | case of laboratory deviations < grade III CTCAE. All other AE/SAE were documented according to ICH GCP guidelines. |
| 19. | **Statistical methods:**<br><br>Primary endpoint analysis: Analysis of the primary endpoint are done on the ITT set using the two-sided Wilcoxon rank sum test (i.e. Mann-Whitney-U test) and the following statistical hypotheses: $H_0$: a = 0 vs. $H_A$: a ≠ 0, where a denotes the shift between the distributions of CCI in the two study groups. The significance level is set to 5%.<br><br>The study protocol planned to impute missing primary endpoint data conservatively. However, since the study was terminated after recruiting just 10% of the planned patients and about half of those recruited patients did not deliver primary endpoint values, it was decided to present the actual values and not to perform the planned imputation. For the same reason we refrain from sensitivity analyses of the primary endpoint.<br><br>Secondary endpoint analysis: All secondary endpoints are presented with appropriate descriptive statistics per study group and listed by patient. No former comparisons between the study groups are done, unless striking effects are observed. In this case the treatment groups will be compared using the Chi-squared test (or Fisher's exact test as appropriate) or the independent samples t-test (or Mann-Whitney-U test as appropriate) depending on the nature of the data. Tests are two-sided at the 5% significance level without correction for multiple comparisons.<br><br>Safety: Safety analyses are done on the ITT set using the actual treatment group. AEs are coded using MedDRA Version English 20.1 and summarized by system organ class and preferred term. SAE and non-SAE-AEs are displayed separately. |
| 20. | **Summary - Conclusions:**<br><br>**Patient demographics and patient disposition**<br>In total 15 patients were included in the study (FPFV: 24.05.2019, LPLV: 28.10.2021).<br>Five of the 15 patients discontinued the study prematurely. Reasons for discontinuation were adverse events (n=1), withdrawal of consent during the course of the study (n=1), death (n=2), and other reasons (n=1).<br>A total of 7 patients were included in Group 1 (with parenteral nutrition) and 8 patients in Group 2 (no parenteral nutrition). The study was completed by 5/7 (71.4%) patients in Group 1 and 5/8 (62.5%) in Group 2.<br>This study included 2 adult (18-64 years, 13.3%) and 13 elderly (65-84 years, 86.7%) patients. The median age was 68 years [range: 41 – 83] in Group 1 and 76.5 years [range: 69 – 83] in Group 2. Group 1 included 3/7 (42.9%) and Group 2 included 2/8 (25.0%) female patients. Distributions of relevant demographics at baseline are given in Tables 1 and 2 (Appendix). |
| | **Compliance:**<br><br>There were no violations of inclusion or exclusion criteria.<br><br>Protocol Violation (PV):<br><br>2 PVs were reported in 2/15 patients. Both PV were rated as minor.<br><br>Two patients received no parenteral nutrition even though they were randomized in Group 1. One patient received parenteral nutrition even though he was randomized in Group 2. |

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| | Adverse events are reported using the actual treatment group. All other analyses are reported as randomized.<br><br>Study medication:<br><br>Adherence to parenteral/no parenteral nutrition:<br>Overall compliance for IMP intake was as expected following clinical routine.<br><br>**Safety Assessments (all patients included)**<br>Annual Safety Reports have been provided to BfArM and EC for the following periods:<br><br>DSUR 1: 18.04.2018-17.04.2019<br>DSUR 2: 18.04.2019-17.04.2020<br>DSUR 3: 18.04.2020-17.04.2021<br>DSUR 4: 18.04.2021-17.04.2022<br><br>Adverse Events and Serious Adverse Events were classified according to CTCAE V. 4.03 and coded according to MedDRA V. 20.1 English. |
| | **Safety Results** (AE, SAE, SUSAR, Late side effects…)<br><br>Safety results are reported in the treatment groups of the actual study treatment, regardless of randomization.<br><br>**Adverse Events (AE)**<br>A total of 28 AEs were reported in 8 (53.3%) of 15 patients see Table 3 (Appendix). 2/6 (33.3%) patients experienced 2 AEs in Group 1 (parenteral nutrition) and 6/9 (66.7%) patients experienced 26 AEs in Group 2 (no parenteral nutrition).<br>No AEs were deemed related to treatment administered (AR).<br>15/28 (53.6%) AEs were rated Grade 1 (mild), 10/28 (35.7%) Grade 2 (moderate), 0/28 Grade 3 (severe), 1/28 (3.6%) Grade 4 (life-threatening), 2/28 (7.1%) Grade 5 (death). Group 1 had only one moderate and one mild AE reported.<br><br>**Serious AE (SAE)**<br>One SAE was reported in one patient in Group 1. Group 2 reported 13 SAEs in 3 patients (Table 4, Appendix).<br><br>**Suspected Serious Adverse Reactions (SAR)**<br>No SAR was reported.<br><br>**Suspected Unexpected Serious Adverse Reactions (SUSAR)**<br>No SUSAR was reported in the study.<br><br>**Non-serious Adverse Events (AE)**<br>A total of 14 non-serious AEs on 5/15 (33.3%) patients were reported during the study. One out of 6 (16.7%) patients in Group 1 experienced one non-SAE AE during the course of the study, whereas in Group 2 13 events were reported in 4/9 (44.4%) patients (see Appendix Table 5 for details) |
| | **Efficacy Results**<br><br>**Primary Endpoint** |

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| | The primary endpoint was analysed on the FAS. Two patients in each study group did not deliver Comprehensive Complication Index (CCI) values on day 30 post surgery, as those patients had no surgery. No imputation of missing values was performed. The CCI in Group 1 had a mean ± SD of 27.1 ± 29.9 and a median of 29.6 with a range from 0 to 72.5 (statistics based on values from 5 patients). The corresponding CCI statistics in Group 2 were mean of 29.8 ± 15.5 and median of 27.8 (8.7 – 47.7) (based on values from 6 patients). This difference was not statistically significant (p = 0.656, Wilcoxon Rank Sum Test). Results of the primary endpoint analyses are shown in appendix Table 6.<br><br>**Secondary Endpoints**<br><br>Three out of five (60.0%) patients in Group 1 who underwent surgery experienced 11 post-surgical complications. This proportion in Group 2 was 6/6 (100%) with a total of 7 complications. Table 7 shows the Clavien-Dindo Classification grade distribution.<br>Only two patients in each treatment group delivered EORTC QLQ-C30 results at Visit 9. There were no baseline differences between the groups (p=0.628). Descriptive statistics can be seen by visit and treatment group in appendix Table 8.<br>Weight and BMI were monitored throughout the study and descriptive statistics can be found in appendix Tables 9 and 10.<br>The median and range of length of hospital stay was 15.5 (12 – 23) days in Group 1 and 15.5 (12 – 111) days in Group 2. The median number of days in ICU was 1 in both groups with ranges (0 – 1) for Group 1 and (0 – 75) for Group 2. |
| | **Overall Conclusion:**<br>This study was stopped after recruiting only 10% of the initially planned number of patients due to poor accrual. No between-group differences could be shown with respect to the primary and the secondary endpoints.<br>Reported AE/SAE were in accordance with the known safety profile of parenteral nutrition solutions administered according to clinical routine to this patient population.<br><br>In conclusion, this study provides no evidence that parenteral nutrition improves postoperative complications measured by the Comprehensive Complication Index. |

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| **21.** | **Date of report:**<br><br>**Date:** _____ **Signature:** _____<br>SDP |

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21. **Date of report:**

**Date:** 16.10.2022 **Signature:** SDP

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# APPENDIX

## Table 1 Demographics and Baseline Characteristics

| | | Treatment group | |
|---|---|---|---|
| | | *Parenteral nutrition (N = 7)* | *No parenteral nutrition (N = 8)* |
| *Sex (n, %)* | *Female* | 3 (42.9%) | 2 (25.0%) |
| | *Male* | 4 (57.1%) | 6 (75.0%) |
| *Age group (n, %)* | *Adults (18 - 64 years)* | 2 (28.6%) | 0 |
| | *Elderly (65 – 84 years)* | 5 (71.4%) | 8 (100%) |
| *Age (years)* | *Mean* | 67.0 | 76.6 |
| | *Std* | 14.6 | 5.2 |
| | *Min* | 41.0 | 69.0 |
| | *Median* | 68.0 | 76.5 |
| | *Max* | 83.0 | 83.0 |
| *Weight (kg)* | *Mean* | 70.6 | 80.5 |
| | *Std* | 20.9 | 18.8 |
| | *Min* | 42.0 | 59.0 |
| | *Median* | 71.0 | 75.0 |
| | *Max* | 100.0 | 113.0 |
| *Height (cm)* | *Mean* | 170.0 | 175.1 |
| | *Std* | 7.8 | 4.7 |
| | *Min* | 160.0 | 170.0 |
| | *Median* | 172.0 | 173.5 |
| | *Max* | 182.0 | 183.0 |
| *BMI* | *Mean* | 24.3 | 26.0 |
| | *Std* | 6.7 | 4.7 |
| | *Min* | 14.9 | 20.4 |
| | *Median* | 24.0 | 25.1 |
| | *Max* | 34.7 | 33.7 |
| *Weight loss during the last 6 months (kg)* | *Mean* | 5.8 | 8.3 |
| | *Std* | 3.8 | 10.2 |
| | *Min* | 0.0 | 0.0 |
| | *Median* | 7.0 | 4.5 |
| | *Max* | 10.0 | 25.0 |

Table 2 TNM Status

| | | *Treatment group* | |
|---|---|---|---|
| | | *Parenteral nutrition (N = 7)* | *No parenteral nutrition (N = 8)* |
| *T (n, %)* | *T2* | 1 (14.3%) | 0 |
| | *T3* | 2 (28.6%) | 4 (50.0%) |
| | *T4* | 1 (14.3%) | 1 (12.5%) |
| | *Tx* | 1 (14.3%) | 0 |
| | *missing* | 2 (28.6%) | 3 (37.5%) |
| *N (n, %)* | *N0* | 0 | 1 (12.5%) |
| | *N1* | 1 (14.3%) | 2 (25.0%) |
| | *N+* | 2 (28.6%) | 2 (25.0%) |
| | *Nx* | 2 (28.6%) | 1 (12.5%) |
| | *missing* | 2 (28.6%) | 2 (25.0%) |
| *M (n, %)* | *M0* | 4 (57.1%) | 4 (50.0%) |
| | *M1* | 0 | 1 (12.5%) |
| | *missing* | 3 (42.9%) | 3 (37.5%) |

**Table 3**: All AEs (grouped by actual treatment)

| | *Exposed to parenteral nutrition N=6* | | *Exposed to no parenteral nutrition N=9* | |
|---|---|---|---|---|
| | | *Subjects affected* | | *Subjects affected* |
| | *Events* | *n (%)* | *Events* | *n (%)* |
| All AEs | 2 | 2 (33) | 26 | 6 (67) |
| SAE | 1 | 1 (17) | 13 | 3 (33) |
| Non-SAE AEs | 1 | 1 (17) | 13 | 4 (44) |

**Table 4**: SAEs (grouped by actual treatment)

| | *Exposed to parenteral nutrition N=6* | | *Exposed to no parenteral nutrition N=9* | |
|---|---|---|---|---|
| | | *Subjects affected* | | *Subjects affected* |
| | *Events* | *n (%)* | *Events* | *n (%)* |
| Cardiac disorders | 0 | 0 (0) | 2 | 1 (11) |
| Atrial fibrillation | 0 | 0 (0) | 1 | 1 (11) |
| Cardiac failure | 0 | 0 (0) | 1 | 1 (11) |
| Gastrointestinal disorders | 0 | 0 (0) | 1 | 1 (11) |
| Diarrhoea | 0 | 0 (0) | 1 | 1 (11) |
| General disorders and administration site conditions | 1 | 1 (17) | 2 | 1 (11) |
| Catheter site extravasation | 0 | 0 (0) | 1 | 1 (11) |
| General physical health deterioration | 1 | 1 (17) | 1 | 1 (11) |
| Hepatobiliary disorders | 0 | 0 (0) | 1 | 1 (11) |
| Hepatic failure | 0 | 0 (0) | 1 | 1 (11) |
| Infections and infestations | 0 | 0 (0) | 4 | 3 (33) |
| Herpes simplex pneumonia | 0 | 0 (0) | 1 | 1 (11) |
| Pneumonia | 0 | 0 (0) | 2 | 2 (22) |
| Sepsis | 0 | 0 (0) | 1 | 1 (11) |
| Renal and urinary disorders | 0 | 0 (0) | 1 | 1 (11) |
| Renal failure | 0 | 0 (0) | 1 | 1 (11) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0 (0) | 2 | 2 (22) |
| Dyspnoea exertional | 0 | 0 (0) | 1 | 1 (11) |
| Respiratory failure | 0 | 0 (0) | 1 | 1 (11) |

**Table 5**: Non-SAE AEs (grouped by actual treatment)

| | *Exposed to parenteral nutrition N=6* | | *Exposed to no parenteral nutrition N=9* | |
|---|---|---|---|---|
| | | *Subjects affected* | | *Subjects affected* |
| | *Events* | *n (%)* | *Events* | *n (%)* |
| Blood and lymphatic system disorders | 0 | 0 (0) | 1 | 1 (11) |
| Thrombocytopenia | 0 | 0 (0) | 1 | 1 (11) |
| Cardiac disorders | 0 | 0 (0) | 1 | 1 (11) |
| Atrial fibrillation | 0 | 0 (0) | 1 | 1 (11) |
| Endocrine disorders | 0 | 0 (0) | 1 | 1 (11) |
| Basedow's disease | 0 | 0 (0) | 1 | 1 (11) |
| Gastrointestinal disorders | 1 | 1 (17) | 2 | 1 (11) |
| Gastrointestinal motility disorder | 0 | 0 (0) | 1 | 1 (11) |
| Melaena | 0 | 0 (0) | 1 | 1 (11) |
| Vomiting | 1 | 1 (17) | 0 | 0 (0) |
| Infections and infestations | 0 | 0 (0) | 1 | 1 (11) |
| Device related infection | 0 | 0 (0) | 1 | 1 (11) |
| Investigations | 0 | 0 (0) | 4 | 1 (11) |
| Blood bilirubin increased | 0 | 0 (0) | 1 | 1 (11) |
| Blood creatinine increased | 0 | 0 (0) | 1 | 1 (11) |
| Blood potassium increased | 0 | 0 (0) | 1 | 1 (11) |
| C-reactive protein increased | 0 | 0 (0) | 1 | 1 (11) |
| Metabolism and nutrition disorders | 0 | 0 (0) | 2 | 2 (22) |
| Hypokalaemia | 0 | 0 (0) | 2 | 2 (22) |
| Skin and subcutaneous tissue disorders | 0 | 0 (0) | 1 | 1 (11) |
| Decubitus ulcer | 0 | 0 (0) | 1 | 1 (11) |

**Table 6**: Comprehensive Complication Index (CCI) at das 30 after surgery

| | | *Treatment group* | |
|---|---|---|---|
| | | *Parenteral nutrition (N = 5)* | *No parenteral nutrition (N = 6)* |
| *CCI* | *Mean* | 27.1 | 29.8 |
| | *Std* | 29.9 | 15.5 |
| | *Min* | 0.0 | 8.7 |
| | *Median* | 29.6 | 27.8 |
| | *Max* | 72.5 | 47.7 |

**Table 7**: Clavien-Dindo Classification

| | | *Treatment group* | |
|---|---|---|---|
| | | *Parenteral nutrition (N = 5)* | *No parenteral nutrition (N = 6)* |
| *CDC (n, %*)* | *Grade 0* | 2 (15.4%) | 0 |
| | *Grade I* | 0 | 3 (25.0%) |
| | *Grade II* | 7 (53.9%) | 5 (41.7%) |
| | *Grade III a* | 3 (28.1%) | 1 (8.3%) |
| | *Grade III b* | 0 | 3 (25.0%) |

** Percentages calculated with respect to the number of non-missing values per group*

**Table 8**: EORTC QLQ-C30

| *EORTC QLQ-C30* | | *Treatment group* | |
|---|---|---|---|
| | | *Parenteral nutrition (N = 7)* | *No parenteral nutrition (N = 8)* |
| *Baseline* | *Valid N* | 7 | 6 |
| | *Mean* | 72.1 | 61.3 |
| | *Std* | 17.1 | 19.9 |
| | *Min* | 46.0 | 38.0 |
| | *Median* | 79.0 | 55.0 |
| | *Max* | 87.0 | 88.0 |
| *Pre-OP* | *Valid N* | 5 | 4 |
| | *Mean* | 66.0 | 63.8 |
| | *Std* | 21.9 | 14.1 |
| | *Min* | 41.0 | 45.0 |
| | *Median* | 61.0 | 65.5 |
| | *Max* | 92.0 | 79.0 |
| *Day 30 post-OP* | *Valid N* | 2 | 2 |
| | *Mean* | 82.5 | 81.5 |
| | *Std* | 2.1 | 3.5 |
| | *Min* | 81.0 | 79.0 |
| | *Median* | 82.5 | 81.5 |
| | *Max* | 84.0 | 84.0 |

**Table 9**: Weight

| *Weight (kg)* | | *Treatment group* | |
|---|---|---|---|
| | | *Parenteral nutrition (N = 7)* | *No parenteral nutrition (N = 8)* |
| *Baseline* | *Valid N* | 7 | 8 |
| | *Mean* | 70.6 | 80.5 |
| | *Std* | 20.9 | 18.8 |
| | *Min* | 42.0 | 59.0 |
| | *Median* | 71.0 | 75.0 |
| | *Max* | 100.0 | 113.0 |
| *Visit 4 (during chemo therapy)* | *Valid N* | 6 | 6 |
| | *Mean* | 68.9 | 79.5 |
| | *Std* | 18.1 | 15.5 |
| | *Min* | 43.0 | 61.0 |
| | *Median* | 66.8 | 77.0 |
| | *Max* | 94.0 | 102.0 |
| *Pre-OP* | *Valid N* | 5 | 6 |
| | *Mean* | 71.2 | 74.8 |
| | *Std* | 18.3 | 12.1 |
| | *Min* | 45.0 | 59.0 |
| | *Median* | 71.0 | 76.5 |
| | *Max* | 92.0 | 93.0 |
| *Visit 7 (Day 7 post OP)* | *Valid N* | 4 | 5 |
| | *Mean* | 64.6 | 78.5 |
| | *Std* | 15.4 | 14.0 |
| | *Min* | 43.3 | 60.0 |
| | *Median* | 67.5 | 80.3 |
| | *Max* | 80.0 | 96.0 |
| *Visit 8 (hospital discharge)* | *Valid N* | 4 | 4 |
| | *Mean* | 62.1 | 75.5 |
| | *Std* | 16.2 | 8.4 |
| | *Min* | 41.5 | 67.0 |
| | *Median* | 63.0 | 74.0 |
| | *Max* | 81.0 | 87.0 |
| *Day 30 post-OP* | *Valid N* | 4 | 3 |
| | *Mean* | 62.9 | 70.0 |
| | *Std* | 20.1 | 10.5 |
| | *Min* | 40.5 | 59.0 |
| | *Median* | 61.0 | 70.9 |
| | *Max* | 89.0 | 80.0 |

**Table 10**: BMI

| *BMI* | | *Treatment group* | |
|---|---|---|---|
| | | *Parenteral nutrition (N = 7)* | *No parenteral nutrition (N = 8)* |
| *Baseline* | *Valid N* | 7 | 8 |
| | *Mean* | 24.3 | 26.0 |
| | *Std* | 6.7 | 4.7 |
| | *Min* | 14.9 | 20.4 |
| | *Median* | 24.0 | 25.1 |
| | *Max* | 34.7 | 33.7 |
| *Visit 4 (during chemo therapy)* | *Valid N* | 6 | 6 |
| | *Mean* | 23.2 | 25.9 |
| | *Std* | 4.7 | 4.0 |
| | *Min* | 15.2 | 21.1 |
| | *Median* | 23.8 | 25.7 |
| | *Max* | 28.4 | 31.5 |
| *Pre-OP* | *Valid N* | 5 | 6 |
| | *Mean* | 23.3 | 24.5 |
| | *Std* | 4.9 | 3.4 |
| | *Min* | 15.9 | 20.4 |
| | *Median* | 24.0 | 24.5 |
| | *Max* | 27.8 | 29.4 |
| *Visit 7 (Day 7 post OP)* | *Valid N* | 4 | 5 |
| | *Mean* | 21.8 | 25.6 |
| | *Std* | 4.6 | 3.5 |
| | *Min* | 15.3 | 20.8 |
| | *Median* | 22.8 | 27.1 |
| | *Max* | 26.1 | 29.6 |
| *Visit 8 (hospital discharge)* | *Valid N* | 4 | 4 |
| | *Mean* | 20.9 | 24.9 |
| | *Std* | 4.8 | 2.1 |
| | *Min* | 14.7 | 22.4 |
| | *Median* | 21.3 | 24.8 |
| | *Max* | 26.4 | 27.5 |
| *Day 30 post-OP* | *Valid N* | 4 | 3 |
| | *Mean* | 21.2 | 23.0 |
| | *Std* | 6.1 | 2.9 |
| | *Min* | 14.4 | 19.7 |
| | *Median* | 20.6 | 24.0 |
| | *Max* | 29.1 | 25.3 |