Nutrition in adult haematology patients with GI mucositis.

Gepubliceerd: 19-11-2013 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24996

Bron
NTR

Verkorte titel
SC29

Aandoening

Chemotherapy induced mucositis
enteral nutrition
parenteral nutrition
stem cell transplantation

Ondersteuning

Primaire sponsor: Radboudumc Nijmegen
Overige ondersteuning: Koningin Wilhelmina Fonds (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

i. Nutritional status determined by change in body-weight.
ii. The severity of GI mucositis as determined by citrulline levels and the Nijmegen Nursing Mucositis Scoring System, NNMSS (APPENDIX B).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Gastrointestinal (GI) mucositis is a severe side effect of chemo- and/or radiotherapy and is associated with nutrient maldigestion and malabsorption. Clinically, patients with mucositis suffer from anorexia, diarrhoea, abdominal pain and weight loss. A standardized, validated and effective feeding strategy for haematology patients suffering from treatment-induced mucositis is currently lacking. However, directed nutritional support might improve the nutritional status of mucositis patients, accelerate recuperation and increase survival. Preclinical studies in rats, suffering from GI mucositis, showed that amino acids and glucose could be normally absorbed especially when administered by continuous enteral drip. The enteral regimen was superior as compared to a parenteral regimen with regards to preservation of gut mucosa integrity. Although there is much experience with both enteral and total parenteral feeding in many clinical settings of patient care, in the care for adults treated with intensive chemotherapy total parenteral nutrition (TPN) is predominantly used. However, no evidence exists indicating superiority of TPN over enteral nutrition (EN) with regards to improved cancer treatment outcome (weight loss, infection incidence and survival). However EN has theoretical benefits including the preservation of the mucosal barrier with less atrophy, bacterial translocation and inflammation. It is easier to administer and cheaper than TPN. Since there are no consistent data about feeding strategies in adults with mucositis, we designed a research project to study which feeding strategy is preferable in patients with chemotherapy-induced mucositis.
Objective: In this study, we will test which of two feeding strategies for adults during chemotherapy-induced mucositis is optimal with regards to maintaining an optimal body weight, nutritional status, gut mucosal barrier and treatment outcome (including complications):

1. An elementary tube diet (Survimed), containing simple macronutrients, administered by continuous enteral drip through a naso-jejunal tube.

2. Total parenteral nutrition administered through a central venous catheter.

Study design: The study will compare two feeding strategies (elementary tube feeding versus total parenteral feeding) in a randomized design. Blinding is not possible due to the nature of the two study strategies (enteral versus parenteral nutrition). TPN is the current clinical practice in adults and therefore designated the standard arm.

Study population: N=40 adults („d 18 years of age), admitted to the Radboudumc for treatment with an autologous haematopoietic stem cell transplantation following conditioning

with high-dose melphalan (HDM) or carmustine, etoposide, cytarabine and melphalan (BEAM).
Intervention: Patients will be given either enteral or parenteral nutrition in a randomized fashion. EN will be administered via a naso-jejunal tube and TPN via a central venous catheter.

Main study parameters/endpoints: Primary endpoints are changes in the nutritional status (bodyweight), and the severity of GI mucositis (daily gut score and citrulline levels). Secondary endpoints include the impact on Quality-of-Life and occurrence of treatment-related complications (neutropenic fever, bacteraemia).

Doel van het onderzoek

Since there are no consistent data about feeding strategies in adults with mucositis, we designed a research project to study which feeding strategy is preferable in patients with chemotherapy-induced mucositis.

Onderzoeksopzet

During hospital stay
After discharge at day 45 en 90 at the outpatient clinic.

Onderzoeksproduct en/of interventie

Enteral nutrition via a naso-jejunal tube (intervention) versus total parenteral nutrition via a central venous catheter (standard care).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Adult patients above the age of 18 able to undergo an autologous SCT with HDM or BEAM.

- Able and willing to give written informed consent.

- Treatment and follow-up at the Radboudumc during the first 6 months after SCT.

- Adequate knowledge of the Dutch language.

- No severe malnutrition; defined as a BMI >18 and/or a serum albumin > 20 g/L.

- No pre-existing bowel diseases e.g. short bowel syndrome, Crohn¡¦s disease, or celiac disease.

- Able to follow the standard infectious protocol.

- Ability to place a naso-jejunal tube.

- Agrees not to use pre- and pro-biotics.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

•Creatinine level > 150 µmol/l, creatinine clearance < 60 ml/min.

• Admission on the hematology department on Wednesday because of tube placement during the weekend.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4069
NTR-old	NTR4270
Ander register	46459 : ABR
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A