Enteral versus parenteral feeding in adult stem cell transplantation patients with chemotherapy-induced gastro-intestinal mucositis.

Published: 02-07-2014
Last updated: 24-04-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON40573

Source
ToetsingOnline

Brief title
SC 29

Condition

- Haematological disorders NEC
- Gastrointestinal conditions NEC
- Appetite and general nutritional disorders

Synonym
mucosal damage digestive tract, mucositis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: KWF

Intervention

Keyword: chemotherapy induced mucositis, enteral nutrition, parenteral nutrition, stem cell transplantation

Outcome measures

Primary outcome

Primary endpoints are changes in the nutritional status (bodyweight), and the

severity of GI mucositis (Nijmegen Nursing Mucositis Scoring System and

citrulline levels).

Secondary outcome

Secondary endpoints include the impact on Quality-of-Life and occurrence of

treatment-related complications (neutropenic fever, bacteraemia).

Study description

Background summary

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.

Study 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.

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.

Study burden and risks

Low risk.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein Zuid 8
Nijmegen 6525GA

NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein Zuid 8
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients admitted to the Radboudumc for treatment with intensive chemotherapy that is known to result in clinically relevant GI mucositis will be eligible for this study. A single cohort has been pre-defined by treatment modality:
- Autologous SCT with either high-dose melphalan (HDM) or carmustine, etoposide, cytarabine and melphalan (BEAM) conditioning for the treatment of multiple myeloma or (non-)Hodgkin lymphoma.
- 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.

Exclusion criteria

-Creatinine level > 150 µmol/l, creatinine clearance < 50 ml/min.

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	02-07-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL46459.091.13
Other	TC=4270

Study results

Date completed:	09-02-2018
Actual enrolment:	40