# Nutrition in adult haematology patients with GI mucositis.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24996

**Source**
NTR

**Brief title**
SC29

**Health condition**

Chemotherapy induced mucositis
enteral nutrition
parenteral nutrition
stem cell transplantation

### Sponsors and support

**Primary sponsor:** Radboudumc Nijmegen
**Source(s) of monetary or material Support:** Koningin Wilhelmina Fonds (KWF)

### Intervention

### Outcome measures

**Primary outcome**

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).

**Secondary outcome**

i. The Quality-of-Life using the EORTC QLQ-C30 version 3.0 (APPENDIX C) and the VAS-score (APPENDIX D).

ii. Body mass index (BMI) and mid-upper-arm circumference (MUAC).

iii. Incidence of infectious complications and bactaeremia.

iv. Inflammatory response as determined by the presence of fever, and elevated levels of C-reactive protein and interleukin-8.

v. Engraftment and time to engraftment.

vi. Percentage of calculated optimal quantity of tube feeding which is actually given to the patient.

vii. Liver toxicity scores according to the NCI-CTCAE version 4.0.

viii. Length of hospital stay

# Study description

**Background summary**

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).

## Study objective

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 design

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

## Intervention

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

# Contacts

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# Eligibility criteria

## Inclusion criteria

- 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.

### Exclusion criteria

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

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

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-09-2014 |
| Enrollment: | 40 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 19-11-2013 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL4069 |
| NTR-old | NTR4270 |
| Other | 46459 : ABR |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A