If the gut works; use it! Malabsorptionmarkers in patients with a haematological-oncological disease after stem cell transplantation, with treatment-related mucositis or graft-versus-host disease of the digestive tract

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Objective: This study objectifies the incidence and quantifies the degree of malabsorption in patients with high dose chemotherapy- or GVHD-induced-mucositis by 2 different valid markers (fecal analyses NIRs and CGT).

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55088

Source
ToetsingOnline

Brief title
MAST - MAlabsorption study before and after Stemcel Transplantation

Condition

- Other condition

Synonym
bloodcancer, hematology

Health condition

Hematologische aandoeningen waarvoor behandeld wordt met een autologe of allogene stamceltransplantatie

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Nationaal Fonds tegen Kanker

Intervention

Keyword: GvHD-DT, Malabsorption, Mucositis

Outcome measures

Primary outcome

Primary endpoint of this study is the incidence of malabsorption and the level of severity of malabsorption in patients with hematological malignancies with chemotherapy- or GVHD-induced-mucositis by standard fecal analysis in combination with dietary (oral/enteral) intake of energy and macronutrients (as percentage intestinal absorption capacity).

Secondary outcome

Secondary endpoints are the accuracy and applicability of fecal volume and citrulline (generation) test (CGT) as markers for malabsorption compared standard procedures (fecal analyses in combination with dietary intake) in these patients.

Study description

Background summary

Malnutrition occurs in up to 45% of patients with hematological malignancies

undergoing allogeneic stem cell transplantation (aSCT) and is negatively associated with clinical outcome, mainly with poor overall survival, increased transplant-related mortality and higher relapse rate. Contrary to other prognostic factors such as age, malnutrition can possibly be influenced by timely dietary intervention, by oral, enteral or parenteral administration. Gastro-intestinal mucositis as a result of chemotherapy or graft versus host disease of the digestive tract (GVHD), are common side effects, which can lead to severe diarrhea. The severe diarrhea that patients experience can be caused by a (partial) failure of the gastrointestinal tract and, in addition to loss of electrolytes and fluid, might be accompanied by loss of nutrients due to an impaired nutrient absorption (=malabsorption). In clinical practice, malabsorption can be objectified and quantified by the intensive method of combining accurate data of oral/enteral food intake (96 hours) and quantifying fecal losses (48-72 hours; volume, energy, fat and nitrogen by gold standard manual techniques as well as recently available *quick and easy* near infrared spectroscopy (NIRs)). Besides, serum citrulline and the citrulline generation test (CGT) are intestinal function markers, however these methods are as yet not validated in patients with hematological malignancies.

Study objective

Objective: This study objectifies the incidence and quantifies the degree of malabsorption in patients with high dose chemotherapy- or GVHD-induced-mucositis by 2 different valid markers (fecal analyses NIRs and CGT).

Study design

Observational, prospective study performed at the inpatient Dept of Hematology of Amsterdam UMC. The expected duration of inclusion for this study is one year.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: During hospital admission data will be collected from electronic patients files already taken for regular patientcare. Patients do not need to visit the hospital for an extra measurement. Fecal collection (48-72 hour) and 72-hour nutritional diary are extra procedures, but former research has shown that it is feasible in patients with hematological malignancies. For CGT, 3 venous blood sample (100 uL) are conducted (fasting, 75 and 90 min after Dipeptiven* administration), purchased through PICC line, which is already placed for hematological treatment. Therefore no added risk are expected.
The risks in participating in this study are negligible. All study procedures included in this study are part of standard clinical care. Although these tests

are not often applied to diagnose malabsorption in patients with hematological malignancies, in clinical practice these tests are widely used, without any associated risks.
The benefit of participating in this study is that patients will undergo diagnostic tests to objectively determine the presence of malabsorption. As soon as malabsorption is detected in our study population, dietary policy can be adjusted accordingly.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Clinical admitted adult patients with hematological malignancies
- Suffer from chemotherapy- or GVHD-induced-mucositis with diarrhea

Exclusion criteria

- Unable to speak, read or write Dutch or English language
- Pregnant or lactating women
- Weight <40 kg
- Comorbidities in which malabsorption can be expected (ao celiac disease, IBD, short bowel syndrome, exocrine pancreatic insufficiency)
- Altered anatomy of the gastrointestinal tract (ao intestinal segment resections, stomata)
- Severe renal impairment (kreatinine clearance < 25 ml/minute), severe hepatic impairment, severe metabolic acidosis or hypersensitivity to the active substance or to N(2)-L-alanyl-L-glutamine.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-06-2022
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL73473.029.20

Study results

Date completed: 01-10-2023

Results posted: 03-12-2024

First publication
03-12-2024