Acute myeloid leukemia and myelodysplatic syndrome: parenteral-, enteral- and only oral nutrition during remission induction treatment

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20839

Source
Nationaal Trial Register

Brief title
AMULET

Health condition

Acute myeloid leukemia and late stage myelodysplastic syndrome

Sponsors and support

Primary sponsor: Maxima MC
Source(s) of monetary or material Support: Vrienden Integrale Oncologische Zorg (VIOZ), Baxter, Fresenius, Maxima MC, Albert Schweitzer Hospital Research Fund

Intervention

Outcome measures

Primary outcome

Body composition (fat mass (index), fat-free mass (index), muscle mass and body fat distribution).

Secondary outcome

Health related quality of life, functional capacity, muscle strength, tolerance of PN, EN and only oral nutrition (i.e. (severity of) nutrition impact symptoms, laboratory serum liver value tests, central venous catheter infections), nutritional status and course of treatment (chemotherapy-induced toxicity, complications, serum liver test abnormalities, duration of hospital stay, treatment-related mortality, progression-free survival, overall survival). Furthermore, patient-, disease- and treatment- characteristics, and data about nutritional intake will be collected.

Study description

Background summary

Intensive treatment of acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) is highly toxic and has considerale gastrintestinal side effects, including anorexia, nausea, vomiting and mucositis often leading to oral pain and severe diarrhea. Hence, most patients experience prolonged periods of minimal inadequate oral intake, diminished nutrient absorption and increased loss of nutrients from the gut, resulting in deterioration of nutritional status. Malnutrition prior to and after hematopoietic stem cell transplantation is associated with hogher complication and lower survival rates. However, due to a lack of studies, especially randomized controlled trials, on nutritional interventions in AML/MDS patients receiving remission induction treatment, there are no evidence-based nutritional guidelines. As a result, there is variability in the use of of parenteral nutrition (PN) and enteral nutrition (EN) among hospitals providing intensive AML/MDS treatment, also in the Netherlands. Whereas some of the hospitals use EN as the first-choice nutritional intervention in AML/MDS patients who cannot achieve adequate oral nutrient intake, others use PN as the preferred route of nutrition administration or have a wait-and-see approach towards both EN and PN, limiting its use to severe and exceptional cases only.
Results from our retrospective study on changes in body weight and serum liver tests associated with PN compared with no PN during remission induction treatment showed better preservation of body weight with frequent versus exceptional use of PN without severe serum liver test abnormalities. However, body weight alone is not a reliable measure for determining nutritional status. In addition, the influence of EN was not investigated, while a few recent studies showed a trend towards fewer complications in enterally versus parenterally fed hematological patients who received intensive treatment. Therefore, in a prospective observational multicentre study, changes in body composition and its influence on muscle strength, functional capacity, quality of life and course of treatment will be investigated in 180 AML/MDS patients who receive EN, PN or only oral nutrition during intensive remission induction chemotherapy treatment. Furthermore, the tolerance of the different nutritional interventions (EN, PN, and only oral nutrition) will be investigated. The

primary outcome measure is body composition (fat mass (index), fat free mass (index), muscle mass, fat distribution), which is measured by: height, body weight (changes), bioelectrical impedance analysis, upper arm (muscle) circumference, triceps skin fold thickness, upper arm fat - and upper arm muscle area, waist circumference, calf circumference). Secondary outcome measures are: functional capacity (6-minute walk test, ECOG / WHO Performance Status), muscle strength (handgrip strength, 30-seconds sit-to-stand test, stairclimb test), quality of life (EORTC QLQ-C30) , tolerance of PN, EN and only oral nutrition (reasons for early cessation of PN/EN, serum liver test values (CTCAEv5.0), central line infections / 1000 catheter days, nutrition impact symptoms (Bristol Stool Chart and CTCAEv4.0 for diarrhea / constipation, CTCAEv4.0 for nausea and vomiting, WHO criteria for oral mucositis, Visual Analog Scale for appetite), nutritional intake (24-hour recall method)), nutritional status (PG-SGA) and course of treatment (complications, length of hospitalization, serum liver test abnormalities, chemotherapy-related toxicity, treatment-related mortality, progression-free survival, overall survival). The outcome measures are measured before, during and after treatment with remission induction chemotherapy.

Study objective

We hypothesize that medical nutrition (PN and EN) compared with no medical nutrition (only oral nutrition) will be associated with better maintenance of nutritional status (fat- and fat free (muscle) mass and body weight), functional capacity, muscle strength, and better course of treatment (shorter duration of hospital admission, reduced chemotherapy-related toxicity, lower complication rates) and quality of life. Furthermore, we expect that EN will be a feasible first-choice nutritional intervention in AML/MDS patients during remission induction chemotherapy, but we expect that PN will be required later on during the treatment process in more than half of the AML/MDS patients treated with remission induction chemotherapy, due to (severe) gastro-intestinal problems.

Study design

Before commencement of remission-induction chemotherapy treatment (baseline), weekly during remission-induction chemotherapy treatment and at the end of remission-induction chemotherapy treatment

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients (≥ 18 years), newly diagnosed with AML or MDS who will start with intensive remission induction chemotherapy

Exclusion criteria

• Patients with cognitive disorders or severe emotional instability
• Patients who are unable to speak, understand or read the Dutch language.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-03-2018
Enrollment:	180
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-04-2020
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	NL8505
Other	METC Maxima MC : METCN17025

Study results