Study of the effects of cytotoxic chemotherapy on oral microcirculation in patients with acute myeloid leukemia (AML)

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

Summary

ID

NL-OMON30919

Source
ToetsingOnline

Brief title
Effects of cytotoxic chemotherapy on oral microcirculation

Condition

- Other condition

Synonym
acute myeloid leukemia, leukemia

Health condition

bloed doorstroming in de microvaten

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acute myeloid leukemia (AML), chemotherapy, microcirculation

Outcome measures

Primary outcome

Noninvasive measurements:

Sidestream Dark-Field (SDF) Imaging * microcirculation quantification

Invasive measurements:

Blood sample * VEGF, bFGF, and MMPs

Secondary outcome

n.v.t.

Study description

Background summary

Mucosal tissues consist of cells that rapidly divide and renew the mucosal lining of the oral and gastrointestinal tract. Studies have suggested that microcirculatory alterations might precede epithelial damage seen in mucositis. One of the principle components of the microcirculation in this respect seems to be damage to the microvascular endothelium. The most debilitating and painful side effect of radiation and chemotherapy is damage to this mucosa, known as mucositis or stomatitis, which has significant impact on health, quality of life, and economic outcomes for the cancer patient. Cytostatic chemotherapeutic and/or antineoplastic drugs endanger patient health by inviting infections (i.e. bacteraemia, fungaemia, and sepsis) and threaten the efficacy of treatment regimes that limit the ability of patients in tolerating

antitumor treatment. Mucositis in its mild form presents an erythematous atrophic lesion with intact mucosa exhibiting redness and nociception equivalent to food-induced burns. Severe mucositis is characterized by ulcerations that penetrate into the submucosa and cause a very painful sensation which usually necessitates narcotic analgesics to manage the patient*s discomfort. Even though the clinical symptoms of mucositis are principally the result of epithelial damage, it is believed that changes in the submucosal endothelium and connective tissue precede epithelial damage. Further more cancer patients receiving any type of invasive medical intervention (i.e. dental intervention, surgery, or accidental traumas) and/or acquisition of any type of wounds, exhibit non- or bad wound healing of tissues.

Study objective

The aim of this study is to elucidate the effects of chemotherapy on the oral microcirculation of patients with acute myeloid leukemia (AML). Ara-C is a stomatotoxic drug that is frequently used in treatment against AML and it can destroy submucosal connective tissue which is closely located to microcirculatory vascular beds. Here are some of the questions we aim to address. What are the effects of cytotoxic chemotherapy on the microvasculature of the oral mucosa in these cases? What is the behavior of the microcirculation, its morphology, and its capillary density in the oral mucosa following chemotherapeutic regimens? We want to test the hypothesis that chemotherapy triggers microcirculatory derangements and this leads to (oral) mucositis in cancer patients.

Study design

In this study we use the technique of sidestream dark-field (SDF) imaging to determine the effects of cytotoxic chemotherapy on the microvasculature of the buccal mucosa in patients receiving standard cytotoxic chemotherapy regimens. Particular attention will be focused on the mean functional capillary density (FCD) of the microcirculation in the oral mucosa of patients receiving cytotoxic chemotherapeutic treatment for acute myeloid leukemia (AML). The investigations that are conducted in this study are designed to assess the microcirculation architecture and its functional status. The SDF imaging device (MicroScan Video Microscope System, MicroScan BV, Amsterdam, The Netherlands) is a mobile and noninvasive technique for studying tissue microcirculation. Additional investigations coupled to this protocol include determination of circulating levels of angiogenic factors such as vascular endothelial growth factor (VEGF), basic fibroblast growth factor (bFGF) and matrix metalloproteinases (MMPs).

1. Measurement time points for the chemotherapy group are:
Day 1 - T0 = before chemo
T1 = 10 minutes after start of first chemo

T2 = 30 minutes after chemo
T3 = 60 minutes after chemo
Days 2, 4, 6, 8

Study burden and risks

n.v.t.

Contacts

Public
Academisch Medisch Centrum

MEIBERGDREEF 9
1105 AZ AMSTERDAM
Nederland
Scientific
Academisch Medisch Centrum

MEIBERGDREEF 9
1105 AZ AMSTERDAM
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. * Patients receiving chemotherapeutic treatment in the Department of Clinical Hematology in the Academic Medical Center (AMC)

2. * Patients with acute myeloid leukemia (AML)
3. * Informed consent from each participating patient
4. * Patients older than 18 years

Exclusion criteria

1. * Severe cardiac and/or pulmonary pathologies
2. * Severe renal function disorders
3. * Hypertension
4. * Patients using anticoagulants or corticosteroids (local or systemic)
5. * Patients with other cancers other than acute myeloid leukemia (AML)
6. * Patients that did not sign an informed consent
7. * Patients younger than 18 years

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

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	NL16457.018.07