Oral mucosal microcirculation measurements in healthy volunteers

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

Summary

ID

NL-OMON43270

Source
ToetsingOnline

Brief title
OMMicHealthVol

Condition

- Other condition

Synonym
Healthy tissue

Health condition

variation in healthy tissue

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Healthy, Microcirculation, Oral mucosa, Volunteers

Outcome measures

Primary outcome

Observations:

Conventional microcirculation data parameters such as total vessel density (TVD), total capillary density (TCD), perfused vessel density (PVD), functional capillary density (FCD), the proportion of perfused vessels (PPV), proportion of perfused capillaries (PPC), microvascular flow index (MFI), heterogeneity index (HI), and blood vessel diameters (BVd) will be analyzed in all digital video image data samples.

Secondary outcome

Not applicable.

Study description

Background summary

Oral mucosal microcirculation is used as a parameter to study a variety of pathologies; the tissue perfusion supporting cellular metabolic process is used as an indicator of tissue health. To identify oral pathological abnormalities associated with the mucosal layer and its embedded microvasculature, a correct index (baseline) of tissue and microvascularity in terms of density, degree of perfusion, architecture, and morphology is vital in order to fully understand the normal variety of these parameters in intact healthy tissue. This way differences in healthy and pathological tissue can be adequately discerned from each other and eventually measured and scored for severity for diagnostic

purposes. Recognizing the pathological appearance of microcirculation is essential to disease signaling, monitoring, and even indicative of treatment response and prediction of treatment outcome.
The CytoCam, an incident dark-field imaging (IDFI) system, consists of a handheld imaging probe (microscope) with a tip connected to a medical computer containing the operational and analyzing software. The images produced by the CytoCam show dark circulating RBCs in vascular lumen flowing against a light background as IDFI is based on hemoglobin absorbing the green light by red blood cells.

Study objective

The aims of this study are to build a database of oral microcirculation data from healthy volunteers between the ages of 18-67 and to compare the datasets between three age groups (18-20, 21-35, 35-67) and gender. An atlas of the microvascular architecture (anatomy) of the different types of oral tissues, average density of vessels in healthy tissue, average diameter of vessels in healthy microcirculation and healthy patterns of flow will be obtained by this observational study (physiology). The generated datasets will serve as an important index of oral vascular health and show the variations seen in healthy tissues. These datasets further will be age-matched and compared with past, present, and future study subjects who have known oral tissue pathologies. To exclude unknown cardiovascular disease that might influence tissue perfusion, neck girth and basic hemodynamic parameters such as blood pressure, heart rate, SpO2, and temperature will also be measured in each healthy volunteer.

Study design

This is a single-center observational clinical investigation of the oral microcirculation in healthy subjects.

Study burden and risks

One time measurement of approximately 6 min. The measurement is non-invasive without discomfort experienced by the human subject.
No benefit for human subject is associated with participation.

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

- ASA 1 and 2 volunteers (smokers, social alcohol drinker, pregnancy, 30- Volunteers that signed an informed consent form
- Volunteers >18 years

Exclusion criteria

- Past history of head and neck malignancy or other relevant pathologies
- Volunteers with known medical history of renal failure, blood dyscrasia or chronic liver disease
of any type, uncontrolled diabetes mellitus and/or hypertension, and HIV infection
- Volunteers on anticoagulants or corticosteroids prior (<15 days) to entry into this study
- Previous history of radiation therapy to the head and neck
- Organ or marrow transplant candidates or recipients
- Volunteers that did not sign an informed consent form
- Volunteers <18 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2016
Enrollment:	600
Type:	Actual

Medical products/devices used

Generic name:	CytoCam;Braedius Medical BV
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-06-2016
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	NL57131.018.16