Verzameling van gegevens over mondgezondheid gedurende een marinemissie van vier maanden.

Gepubliceerd: 11-08-2017 Laatst bijgewerkt: 15-05-2024

The primary objective of this study is to evaluate changes in oral health during a 4-month naval mission and once one month thereafter.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21281

Bron
Nationaal Trial Register

Verkorte titel
OHMIR

Aandoening

Microbiome shifts, Mucosal inflammation, Periodontal health, Gingival inflammation, Stress, Oral parafunctions

Ondersteuning

Primaire sponsor: ACTA Dental Research B.V. (ADR)
Gustav Mahlerlaan 3004
1081 LA Amsterdam, NL
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Overige ondersteuning: Ministerie van Defensie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter and indicator of oral health is bleeding of the gingiva on probing (BOP; gingival inflammation).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Oral health problems are a major concern for military personnel, especially when deployed in remote regions of the world. Prior to taking part in a mission, military personnel is required to meet certain standards in oral health status, as outlined in the NATO issued dental fitness protocol. Nevertheless, military dentists frequently report mucosal inflammation (oral ulcers), fungal oral infections and gingival bleeding among personnel during a mission. In scientific literature, also reports can be found of non-military expeditions, reporting increased gingival bleeding, and oral ulcers. It has been suggested that stress, changes in diet and lifestyle along with reduced levels of personal care during mission can lead to deterioration of oral health status, but scientific data about the causes are largely lacking. In addition, it has also been reported that the composition of the oral microbial community is predictive for the development of oral disease under stress.

Objective: The primary objective of this study is to monitor changes in oral health during a 4-month naval mission and once approxemately one month thereafter. The secondary objectives are to correlate possible changes compared to the baseline measurements to lifestyle, diet and stress. Finally, to assess whether microbiome composition can predict changes in oral health or general health.

Study design: prospective observational cohort study

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: the burden exists of seven site visits of about 30 minutes. Examinations are non-invasive and do not cause physical discomfort. The subjects will complete one questionnaire per visit, with questions regarding general health, sleep, stress, physical activity, food intake and disorders of the temporomandibular joint. Participation does not benefit the subjects. The risks are negligible. The study is group-related because the research questions can only be answered in a cohort where food, circadian rhythm and stress from the mission assignment

are controlled.

Doel van het onderzoek

The primary objective of this study is to evaluate changes in oral health during a 4-month naval mission and once one month thereafter.

Onderzoeksopzet

Visit 1 – within the first two weeks of the mission (baseline)

Visit 2 to 4 – every 2 to 3 weeks (average 2.5 weeks) during the mission

Visit 5 – within the last two weeks of the mission (end of mission visit)

Visit 6 – within 9 weeks (± 3 weeks) after the end of the mission

Onderzoeksproduct en/of interventie

This is an observational study, without any interventions.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All Dutch service members participating are declared fit to participate in the naval mission, every service member of the mission is a potential subject. Only with written informed consent a potential subject can participate in this study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject that meets any of the following criteria is to be excluded from participation in this study:

- carrier of removable partial dentures

- carrier of a removable night guard

- use of antibiotics three months prior to the mission

- use of anti-inflammatory drugs on a regular basis (NSAIDs)

- adverse medical history or long-term medication

- prescribed medication (except for contraceptives)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2017
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	11-08-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44394
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6430
NTR-old	NTR6608
CCMO	NL62301.048.17

Register	ID
OMON	NL-OMON44394

Resultaten