Effect of daily vitamin C supplementation with or without flavonoid supplements on periodontal and systemic conditions before and after periodontal treatment

Published: 24-05-2018
Last updated: 10-04-2024

To evaluate the inflammatory reducing effect, in the periodontal tissues and systemically, of vitamin C with quercetin and other flavonoids in untreated periodontal disease. Secondly to evaluate the effect of vitamin C with quercetin and other…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON46353

Source
ToetsingOnline

Brief title
Quercetin Supplements in Initial Periodontal Treatment (QSIPT)

Condition

- Bacterial infectious disorders

Synonym
gum disease, periodontitis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam

Source(s) of monetary or material Support: Ministerie van OC&W,Eklund Foundation

Intervention

Keyword: Flavonoid, Periodontitis, Quercetin, Vitamin C

Outcome measures

Primary outcome

Clinical measurements:

bleeding on pocket probing (bop),

Secondary outcome

Clinical measurements:

probing pocket depth (ppd),

clinical attachment level (cal),

gingival recessions (rec),

plaque (plq),

tooth mobility (mob),

pocket suppuration (sup).

Lab variables:

Subgingival microbiological profile (analyses by 16S rRNA gene amplicon

sequencing by Illumina Miseq platform),

Systemic biomarkers HbA1C, hs-CRP, and vitamin C (from venous blood).

high density lipids (hdl)

low density lipids (ldl)

creatinine (crea)

triglycerides (trigl)

General measurements:

Body mass index (bmi)

Waist circumference (wc)

Bloodpressure (bp)

Study description

Background summary

An important aim of the periodontal professional is to improve and promote periodontal health as part of oral health, general health and well-being. Research of the last decades showed that smoking, stress, and an unhealthy diet have a detrimental effect on the periodontal condition. Periodontitis patients have lower plasma levels of vitamin C compared to healthy controls. In addition, a correlation has been found between the level of vitamin C in the diet and the level of vitamin C in plasma of healthy controls. In periodontitis patients this correlation was not found. The studies by Van der Velden et al. (2006) on the natural history of periodontitis in people living in Java, who had no access to dental care are well known. In this population the severity of periodontitis appeared to be related to the consumption of guava fruit. The more guava fruits were consumed, the less the severity of periodontitis. Guava fruit contains an extremely high concentration of vitamin C and in addition many flavonoids, among others quercetin. Quercetin has a number of characteristics that could explain the possible positive effect of guava fruit on the periodontal condition. The initial periodontal treatment is the most important therapy for our periodontal patients. It consist of supra- and subgingival plaque and calculus removal as well as thorough oral hygiene instruction. An additional aim in the treatment of periodontitis is improving the host resistance. In this respect smoking cessation and reduction of stress

have been studied extensively. Also, a healthy diet consisting of fruits and vegetables contributes to an improved host resistance. On the basis of the above it may be suggested that vitamin C with or without quercetin supplementation could improve the periodontal resistance and thereby the results of periodontal therapy.

Study objective

To evaluate the inflammatory reducing effect, in the periodontal tissues and systemically, of vitamin C with quercetin and other flavonoids in untreated periodontal disease.
Secondly to evaluate the effect of vitamin C with quercetin and other flavonoids compared to vitamin C alone on periodontal and systemic parameters as an adjunct to initial periodontal therapy.

Study design

A single blind parallel randomized controlled longitudinal study.

Intervention

The intervention will be the daily intake of vitamin C with flavonoids supplements (capsules) (test group 1), or vitamin C only supplements (capsules) (test group 2), compared to a negative control group. This negative control group will be provided with non-active fibers only (capsules). The intake of the supplements will be as long as the total duration of the study i.e. 5 months.

After informed consent is obtained, participants do not recieve any periodontal treatment yet. Two months is the typical duration of 'waiting time' between intake and the first appointments. Two months after intake all groups will receive initial periodontal therapy, which will be performed within 2 weeks. During the following 3 months, all groups will continue with taking the supplements. All groups will receive oral hygiene reinforcement during this period. Evaluation measurements will be carried out at intake (T0), start of initial therapy (T1) and 3 months (T2) after the last initial treatment session.

Study burden and risks

All groups recieve the regular treatment as they would when not taking part in the study. This initial treatment is in fact the treatment for which patients are referred. This is not considered as a burden nor involves any risks. For all groups there is no difference compared to this normal treatment. The only extra burden is three times venous blood drawing, and the daily intake of

supplements. Intake of these supplements is not associated with any risks.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age: >=18 years;
- proximal bone loss of > 3mm in 2 non-adjacent teeth,
- probing pocket depth > 3 mm and bleeding on probing on at least 25% of their total sites and documented radiographic bone loss,
- good general health.

Exclusion criteria

- diagnosis of any acute periodontal problem which requires immediate treatment;
- use of antibiotics within the previous 6 months;
- pregnant or lactating women;
- previous initial periodontal treatment within the last year;
- current orthodontic treatment;
- use of any medication which may interfere with quercetin, or with the study outcomes.*
- current daily use of supplements containing vitamin C
- patients who have had immunotherapy (<3 months before appointment) or who need treatment for malignancy
- patients who have been irradiated in head and neck area
- patients in whom the immune response has been compromised (eg Papillon Lefèvre syndrome)
- patients who are unable to provide oral hygiene themselves (physically or mentally handicapped)
- patients with a jaw resection done
- patients with Sjögren's syndrome

* Antibiotics (incl. Prophylaxis) and regular use (more than once a week) of anti-inflammatory drugs, steroidal anti-inflammatory drugs (NSAIDs, namely Ibuprofen, Diclofenac, Acetylsalicylic acid, Naproxen) and non-steroidal anti-inflammatory drugs (corticosteroids).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-08-2018
Enrollment:	81

Type:	Actual

Ethics review

Approved WMO Date:	24-05-2018
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	NL63480.029.18