The effect of daily dietary intake of dried whole food concentrates of fruit, vegetables and berries (Juice Plus+®) upon periodontal outcomes in chronic periodontitis: a Multi-centre RCT.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34567

Source
ToetsingOnline

Brief title
MULTI-NSA-10-001 ENURGISE

Condition

- Other condition
- Bacterial infectious disorders

Synonym
gum disease, periodontitis

Health condition

parodontitis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: contract met industrie (de producent van de voedingssupplementen). ACTA is "subcontractor" van het hoofdcentrum in Birmingham;UK.,NSA LCC, 140 Crescent drive, Collierville, Tennessee 38017, VS

Intervention

Keyword: concentrates, diet, periodontitis

Outcome measures

Primary outcome

Clinical parameters of the periodontal condition: Modifief gingival index

(MGI), Marginal bleeding on probing, Probing Pocket depth (PPD),

quality-of-life assessment.

Secondary outcome

Other clinical parameters: % bleeding sites, recession, attachment level,

plaque scores.

Biochemical parameters: levels of vit. C and beta carotene, hsCRP, number of

leukocytes, glucose, insulin, fibrinogen, HbA1c, cholesterol, triglycerides

Study description

Background summary

Approximately 10% of the Dutch population is susceptible to developing severe periodontitis. This disease, if untreated, will cause inevitably loss of alveolar bone and finally loss of teeth.
The individual susceptibility to periodontitis is determined by a number of factors amongst others genetic predisposition, smoking and stress. In the light of new research data it seems that nutrition could as well be related to this

susceptibility. In particular, it seemed that the levels of certain vitamins in the blood are lower in periodontitis patients that their healthy counterparts. A company produces food supplements regulated by FDA (Food and Drug Administration, USA) and rules dictated by the European Union. The concentrate(Juice Plus+®) is used for 15 years without any reported side-effects.
The question is whether daily use of these foof supplements will reduce the severity of periodontitis (3 months observational period) and whether the result of the periodontal treatment will be better in periodontitis patients that use these supplements.

Study objective

We want to investigate the hypothesis that daily use of the above mentioned supplements (consisted of concentrated fruit en vegetables) results in improved healing of periodontal tissues in patients suffering from periodontitis.
Besides we investigate " patient centered outcomes" by means of a quality-of-life questionnaire. This investigation is performed in a multi-center design where ACTA is one of the centers.

Study design

parallel randomized double blind placebo control

Intervention

17 patients will receive the test product: twice daily 3 capsules (Juice Plus+®)
The other 17 patients will receive a placebo.

Study burden and risks

Inconvenience and risks for the participants:
* Preliminary selection: telephonic interview (10 min)
* 1st appointment (60 min): medical and dental anamneses, quality of life assessment questionnaire, clinical and laboratory parameters
* Short telephonic conversation after 2 weeks (5 min)
* 2nd appointments after 6 weeks: inspection oral cavity, short conversation (15 min)
* 3rd appointment after 3 months (60 min): quality of life assessment, clinical and laboratory parameters
* Treatment by Staff (3-4 appointments depending on the situation)
* 4th appointment (60 min): quality of life assessment questionnaire, clinical and laboratory parameters

* No risks, except for minor discomfort after blood taking (small hematoma) and some slight stomach discomfort, this is the reason we advise to take the products with full stomach.

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

* be aged 18 and over;
* have a minimum of 20 teeth,
* have chronic periodontitis
* be capable of giving informed consent themselves.

Exclusion criteria

* less than 20 teeth
* pregnancy or breast feading
* complexe medical background
* long-term use of antibacterial- or anti-inflammatory medication
* unable to use the capsules the way they are prescribed
* regular use of vitamin supplements

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	34
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	NL32599.018.10