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The adjunctive effects of Omega-3 dietary supplementation in the treatment of periodontitis

Submission date	Recruitment status	[_] Prospectively registered
27/07/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/11/2015	Digestive System	

Plain English summary of protocol

Background and study aims
If you have gum disease, your gums become swollen, sore or infected and may bleed when you brush your teeth, and you may have bad breath. This stage of gum disease is known as gingivitis. If gingivitis is not treated, a condition called periodontitis can develop, which can lead to the bone in your jaw to decay and your teeth to fall out. Periodontitis is diagnosed once irreversible tissue destruction has already occurred, so we need to find a way to diagnose the disease at an earlier stage. The aim of this study was to assess the levels of signalling proteins called cytokines in fluid sampled from the inflamed gums of patients with gingivitis and periodontitis. The secondary aim was to investigate the effect of periodontal treatment with and without omega-3 supplementation on the cytokine levels and the bone density of the tooth sockets.

Who can participate?
Adults aged over 18 with periodontitis or gingivitis.

What does the study involve?
Periodontitis patients were randomly allocated to take either omega-3 supplements or placebo (dummy) tablets for 4 months. All patients received oral hygiene instructions and scaling and root planing (deep cleaning between the gums and the teeth down to the roots) under local anesthestic. Fluid was sampled from the gums of gingivitis patients and periodontitis patients and the levels of cytokines were analyzed in the lab.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Rio de Janeiro State University (Brazil).

When is the study starting and how long is it expected to run for?
October 2010 to October 2012.

Who is funding the study?
National Council for Scientific and Technological Development (Brazil).

Who is the main contact?
Dr Gisele Martinez

Contact information

Type(s)
Scientific

Contact name
Dr Gisele Martinez

ORCID ID
https://orcid.org/0000-0002-9503-2261

Contact details
SQSW 303 BL G APTO 305 Sudoeste
Brasília
Brazil
70673307

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The adjunctive effects of Omega-3 dietary supplementation in the treatment of periodontitis: a clinical and immunological study

Study objectives
The general aim of this randomized controlled double-blind trial was to test the hypothesis that an adjunct dietary supplementation of Omega-3 on chronic periodontitis non-surgical treatment improves clinical and immunological outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Pedro Ernesto University Hospital, 15/12/2010, protocol 2714/2010

Study design
Parallel double-blinded randomized controlled trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Periodontal diseases, gingivitis and periodontitis

Interventions
Periodontitis patients were randomized using a coin toss into 4 months supplementation with omega-3 or placebo in a parallel double-blinded design. All patients received non-surgical periodontal treatment which consisted of oral hygiene instructions and supra- and sub-gingival scaling and root planing (SRP) under local anesthesia. The treatment was performed by an experienced periodontist (GLM) with manual (Gracey and McCall curettes, Hu-Friedy, Chicago, IL, USA) and ultrasonic (Cavitron select, Dentsply, York, PA, USA) instruments. On average, the treatment required four 50-min sessions. The intervention group received omega-3 dietary supplementation (3 capsules of 300 mg omega-3 (180 mg EPA/120 mg DHA)/day), and the control group received placebo (3 capsules of 450 mg gelatin/day) (Quintaessencia, Rio de Janeiro, Brazil). Patients of both groups received three containers of 30 capsules/month. Compliance was assessed by the return of empty containers, and assessed weekly at visits to the clinic or by telephone calls. The bottles were not decoded until follow-up evaluations and analyses had been performed to ensure a proper double-blind study protocol.

Intervention Type
Supplement

Primary outcome(s)
Periodontal examination included bleeding on probing (BOP), O'Leary's plaque index (PI), probing depth (PD), and clinical attachment level (CAL). The PD and CAL were recorded at 6 sites per tooth (mesio-buccal, mid-buccal, disto-buccal, mesio-lingual, mid-lingual, and disto-lingual), excluding the third molars, using a periodontal computerized probe (Florida Probe, Gainesville, FL, USA). The intra-examiner concordance was 98% within the interval of ± 0.5 mm for PD and CAL. Timepoints: baseline, 4th month and 12th month

Key secondary outcome(s))
Gingival crevicular fluid was collected between 8 h and 12 h as previously described [Figueredo and Gustafsson 1998]. Measurements of a panel of cytokines and chemokines in GCF were performed using a Luminex 200 analyzer (Alameda, CA, USA) with Milliplex kits (Millipore, Billerica, MA, USA) according to the manufacturer’s instructions. Fifty μL of GCF was used to analyze the levels of IL-1β, IL-2, IL-4, IL-6, IL-8, IL-10, interferon (IFN)-γ, osteocalcin (OC), osteoprotegerin (OPG) and RANK-L. Timepoints: baseline, 4th month and 12th month

Completion date
01/10/2012

Eligibility

Key inclusion criteria
1. Adults aged over 18 with generalized chronic periodontitis seeking treatment at the dental school of the Rio de Janeiro State University (UERJ), Rio de Janeiro, Brazil between 2010 and

2011. An experienced specialist in periodontology diagnosed patients according to the criteria of the American Academy of Periodontology (AAP).
2. Having moderate-severe periodontitis (attachment loss ≥ 3 mm and periodontal pocket ≥ 5 mm) in at least 4 interproximal sites from different teeth, and having at least 15 own teeth
3. A group of plaque-induced gingivitis patients was used as controls: at least 20 own teeth with no interproximal attachment loss and presence of bleeding in ≥ 30% of sites

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Diagnosed systemic disease
2. The use of antibiotics or non-steroidal anti-inflammatory drugs (NSAIDs) in the previous 6 and 3 months, respectively
3. Ongoing use of medication known to affect periodontal condition such as anticonvulsants (phenytoin) or immunosuppressives (cyclosporine, nifedipine, nitrendipine, oxidipine, felodipine, amlodipine, verapamil and diltiazem)
4. Ongoing use of omega nutritional supplements, or previous periodontal and/or orthodontic treatment in the last 12 months

Date of first enrolment
01/10/2010

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
Brazil

Study participating centre
Rio de Janeiro State University (UERJ)
Brazil
20551-030

Sponsor information

Organisation
Rio de Janeiro State University (UERJ) (Brazil)

ROR
https://ror.org/0198v2949

Funder(s)

Funder type
Government

Funder Name
Conselho Nacional de Desenvolvimento Científico e Tecnológico

Alternative Name(s)
Brazilian National Council for Research and Development, National Council for Scientific and Technological Development, CNPq - Conselho Nacional de Desenvolvimento Científico e Tecnológico, National Council for Scientific and Technological Development (Conselho Nacional de Desenvolvimento Científico e Tecnológico), CNPq

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Brazil

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014		Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes