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P. gingivalis passive immunization using egg yolk antibodies

Submission date 20/03/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/03/2015	**Overall study status** Completed	
Last Edited 09/10/2015	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Periodontal (gum) disease is very common, Over time, it can cause the bone in the jaw holding the teeth to decay; the teeth can become loose and eventually fall out. It can be prevented by tooth brushing, using dental floss and other devices designed to remove bacterial plaque from the teeth. However, these measures are often not performed well enough to remove all plaque from the teeth. It is therefore thought that a chemical plaque control method may be of benefit. Porphyromonas gingivalis is thought to be the bacteria that causes most cases of periodontitis. Gingipain is an enzyme that is believed is needed for P. gingivalis to survive and grow in the mouth long enough to cause disease. Anti-Porphyromonas gingivalis egg yolk antibody (IgY-GP) can inhibit the activity of gingipain. In this study, we wanted to investigate how well tablets containing IgY-GP can treat periodontitis when combined with scaling and root planning.

Who can participate?
Healthy adult volunteers with periodontal disease.

What does the study involve?
All participants have their teeth and gums checked for periodontal disease and clinical measures taken. Two weeks after this, all participants are given full-mouth scaling and root planning treatment. Participants are then randomly allocated into one of two groups. Those in group 1 receive the IgY-GP tablets three times a day after a meal or brushing. Participants in group 2 receive placebo tablets. Each participant in both groups are followed up 4 weeks and then 12 weeks after treatment to check for periodontal disease and periodontitis causing bacteria in the mouth.

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

Where is the study run from?
Nihon University School of Dentistry (Japan)

When is the study starting and how long is it expected to run for?
May 2008 to September 2008

Who is funding the study?
Sato Fund, Nihon University School of Dentistry (Japan)

Who is the main contact?
Professor Naoyuki Sugano

Contact information

Type(s)
Scientific

Contact name
Prof Naoyuki Sugano

Contact details
1-8-13 Kanda-Surugadai
Chiyoda-ku, Tokyo
Japan
101-8310

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of anti-porphyromonas gingivalis egg yolk antibodies in patients with periodontal disease

Study objectives
In this study, we investigated the efficacy of IgY-GP-containing tablets as an adjunct to periodontal treatment in patients with periodontitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nihon University School of Dentistry Institutional Review Board 2006-9

Study design
Randomized double-blind placebo controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Periodontal disease

Interventions
Eligible subjects (mean age, 51.0 ± 8.5 years; range, 36-66 years) were allocated randomly to the test and control groups according to gender, age, and smoking status, using a randomization table. All subjects had at least two probing pockets with a depth of ≥4 mm and bled after probing. All participants provided written informed consent. The study protocol was a double-blind placebo-controlled trial and approved by the Nihon University School of Dentistry Institutional Review Board. The randomization code was revealed when all microbiological and clinical data were gathered after the 12-week intervention period. Participants were instructed not to change their oral hygiene regimens, and tooth brushing instruction was not given during or before the experimental period.

Clinical measurements were obtained for Ramfjord's six teeth (16, 21, 24, 36, 41, and 44 in the FDI two-digit notation system) in all subjects). The deepest probing depth (DPD), mean probing depth (PD), bleeding on probing (BOP), and O'Leary plaque control record (PCR) were recorded. When one of the selected teeth was missing from the oral cavity, data were obtained from an adjacent tooth in the same area of the jaw. Two weeks after the first clinical measurement, all participants received full-mouth scaling and root planning, followed by professional mechanical tooth cleaning (PMTC). All procedures were performed by two trained periodontists. After that, the subjects in the test (IgY-GP) group took tablets containing anti-gingipain egg yolk antibodies (100 mg/tablet), without chewing, three times a day after a meal or brushing. Tablets stayed in the mouth for 3 to 5 minutes. Eight hours after two minutes mouth rinse with egg yolk immunoglobulin, active antibodies detected in the saliva from 18 of 19 subjects. The subjects in the control group took placebo tablets containing non-immunized egg yolk antibodies in the same manner.

Intervention Type
Biological/Vaccine

Primary outcome measure
Periodontal tissue conditions

Measured at baseline, 4 weeks and 12 weeks.

Secondary outcome measures

Periodontopathic bacterial number

Measured at baseline, 4 weeks and 12 weeks.

Overall study start date
01/05/2008

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. At least 2 sites of peridontal disease

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Less than 20 teeth
2. Taking medicine
3. Systematic disease
4. Food allergy
5. Need dental treatment

Date of first enrolment
01/05/2008

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
Japan

Study participating centre
Nihon University School of Dentistry
1-8-13 Kanda-Surugadai, Chiyoda-ku

Tokyo
Japan
101-8310

Sponsor information

Organisation
Nihon University School of Dentistry

Sponsor details
1-8-13 Kanda-Surugadai, Chiyoda-ku
Tokyo
Japan
101-8310

Sponsor type
University/education

ROR
https://ror.org/05jk51a88

Funder(s)

Funder type
University/education

Funder Name
Sato Fund, Nihon University School of Dentistry (Japan)

Funder Name
Ministry of Education, Culture, Sports, Science and Technology-Japan

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request