

P. gingivalis passive immunization using egg yolk antibodies

Submission date 20/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/10/2015	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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 (PMTTC). 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(s)

Periodontal tissue conditions

Measured at baseline, 4 weeks and 12 weeks.

Key secondary outcome(s)

Periodontopathic bacterial number

Measured at baseline, 4 weeks and 12 weeks.

Completion date

30/09/2008

Eligibility

Key inclusion criteria

1. At least 2 sites of periodontal disease

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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Sponsor information

Organisation

Nihon University School of Dentistry

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request