

Dental Scaling and Root Planning Improve Allergies

Submission date 09/04/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/04/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/02/2020	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In the 21st century there is an urgent need to apply new strategies to prevent allergic diseases among children. Children with gum disease (gingivitis) often have house dust mite allergy. A strategy to eliminate the substance that causes the allergic reaction (allergen) could be dental scaling and root planning.

This study aims to investigate the beneficial effects of 6 months dental scaling and root planning at reducing the negative reaction to the dust mite allergy.

Who can participate?

Children aged 6-16 years with gingivitis and house dustmite allergy

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive a monthly session for a scaling and root planning program. Those in the second group receive standard treatment, which includes a toothpaste and monthly consultation with an experienced doctor. This lasts for 6 months. Participants in the second group can then receive the intervention program too.

Participants have a blood sample taken at the start, and after the 6 months.

What are the possible benefits and risks of participating?

Participants benefit from free dental consultation and examination, free scaling and root planning from well-experienced dentists, along with a research subject's fee. A possible risk of participating in this study is hematoma caused by phlebotomist, since we would like to carry blood sample twice

Where is the study run from?

Faculty of Dental Medicine Universitas Airlangga - Dr. Soetomo General Hospital (Indonesia)

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

January 2017 – December 2017

Who is funding the study?
Faculty of Dental Medicine, Universitas Airlangga (Indonesia)

Who is the main contact?
Sindy Cornelia Nelwan (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20/Panke.KKE/I/2017

Study information

Scientific Title
Effect of Comprehensive Six Months Dental Scaling and Root Planning To Improve Biomolecular Markers of Atopy in Gingivitis Children with House Dust Mite Allergy

Study objectives
Dental scaling and root planning may improve biomolecular markers of atopy by decreasing level of IgE and IgG4 in subjects serum.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Dr. Soetomo General Hospital Ethics Committee for Health Research, 20/01/2017, ref: 20/Panke. KKE/I/2017

Study design

Investigator-initiated randomized non-blinded placebo-controlled trial with two-group pretest and repeated posttest superiority-group experimental design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Periodontitis

Interventions

Participants are randomly allocated to one of two groups. Those in the intervention group receive a comprehensive 6 months dental scaling and root planning treatment program, as well as standard treatment. Scaling and Root Planning is performed by a well-experienced physician from Department of Pediatric Dentistry, Faculty of Dental Medicine Universitas Airlangga - Dr. Soetomo General Hospital, using an ultrasonic scaler. Participants attend a dental session monthly.

Those in the control group receive only standard treatment.

Standard treatment includes toothpaste containing fluoride and triclosan, and monthly consultation with a well-experienced physician.

Intervention Type

Procedure/Surgery

Primary outcome measure

IgE is measured from a blood sample at baseline and 6 months

Secondary outcome measures

IgG4 is measured from a blood sample at baseline and 6 months

Overall study start date

01/01/2017

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Children aged 6-16 years of any gender and ethnicity
2. Diagnosed with HDM allergies by positive skin-prick test
3. Diagnosed with gingivitis by >2 plaque index according to Silness-Löe criteria
4. High baseline IgE titer (>90 pg/ml), suggesting a positive childhood allergic potency
5. Understand and able to cooperate to the research protocol
6. Parents give voluntary, signed written consent in accordance with our institutional policies

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

10

Total final enrolment

10

Key exclusion criteria

1. Taking any antihistamines or steroid which commonly interferes with results of skin-prick within one month
2. Previously experienced any immunotherapy procedures
3. Previously experienced dental scaling and root planning within 6 months
4. Presence of low grade fever due to infections rather than gingivitis
5. Recent blood disorders or congenital abnormalities
6. Any medical conditions that may be harmful if involved in this study

Date of first enrolment

31/01/2017

Date of final enrolment

28/02/2017

Locations

Countries of recruitment

Indonesia

Study participating centre

Dr. Soetomo General Hospital

Jalan Mayjen Prof. Dr. Moestopo 6-8

Surabaya

Indonesia

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Study participating centre

Universitas Airlangga

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Sponsor information

Organisation

Faculty of Dental Medicine Universitas Airlangga

Sponsor details

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University/education

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<https://ror.org/04ctejd88>

Funder(s)

Funder type

University/education

Funder Name

Faculty of Dental Medicine Universitas Airlangga

Results and Publications

Publication and dissemination plan

Intended publication at Periodontology 2000

Intention to publish date

01/06/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Author Sindy Cornelia Nelwan (sindy-c-n@fkg.unair.ac.id)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	17/02/2020	Yes	No