

# Dental Scaling and Root Planning Improve Allergies

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<b>Registration date</b> 17/04/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/02/2020	<b>Condition category</b> 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)  
sindy-c-n@fkg.unair.ac.id

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Sindy Nelwan

**ORCID ID**  
<https://orcid.org/0000-0001-7829-6524>

**Contact details**  
Jalan Mayjen Prof. Dr. Moestopo 47  
Surabaya  
Indonesia  
60135  
+62 811 346979  
sindy-c-n@fkg.unair.ac.id

## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

16 years

**Sex**

All

**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

60135

**Study participating centre****Universitas Airlangga**

Jalan Mayjen Prof. Dr. Moestopo 47

Surabaya

Indonesia  
60135

## Sponsor information

### Organisation

Faculty of Dental Medicine Universitas Airlangga

### ROR

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

## Funder(s)

### Funder type

University/education

### Funder Name

Faculty of Dental Medicine Universitas Airlangga

## Results and Publications

### 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](mailto: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?
<a href="#">Results article</a>	results	01/12/2019	17/02/2020	Yes	No