Can vitamin supplements help school children in healing gum diseases?

Submission date	Recruitment status	Prospectively registered
31/05/2025	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
05/08/2025	Completed	Results
Last Edited	Condition category	Individual participant data
13/06/2025	Oral Health	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Gum disease is very common in Pakistani children. Along with the lack of dental hygiene awareness and regular checkups, deficiencies in micronutrients like vitamin C and D are also widespread among children. This study aimed to assess whether correcting the micronutrient deficiency alongside normal dental care would improve periodontal disease progression in school-age children.

Who can participate?

School-going children aged 4-12 years with no systemic illnesses

What does the study involve?

First visit (baseline): each child (and a parent) answers a short questionnaire about home dental habits, demographics, and vitamin deficiency and then has a dental checkup.

Group allocation:

Group A (control): professional ultrasonic scaling + dental hygiene advice.

Group B (vitamin C and D deficient group): the same scaling and advice plus vitamin C & D supplements.

Follow-up visits: after 4 weeks and again after 8 weeks the dentists re-measure the Gingival Index and pocket depth. All children receive the same brushing advice at every visit.

What are the possible benefits and risks of participating?

Benefits: free dental scaling, personalised brushing tips, and (for Group B) free vitamin supplements that may reduce the severity of gum disease.

Risks: scaling can feel a little sensitive and vitamins can occasionally cause mild stomach upset, but no serious risks are expected. The university ethics board has stated that there is no disadvantage or risk for participants and families may leave the study at any time.

Where is the study run from?

Dental examinations take place in selected primary schools in Lahore and at the University Dental Hospital, University College of Medicine & Dentistry (UCMD), The University of Lahore (Pakistan).

When is the study starting and how long is it expected to run for? September 2021 to February 2024

Who is funding the study? Investigator initiated and funded

Who is the main contact? Dr Arooj ul Hassan, arooj.ulhassan@ucd.uol.edu.pk, aroojch678@hotmail.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Arooj Ul Hassan

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

00001

Study information

Scientific Title

Effectiveness of Vitamin C and Vitamin D supplements in the treatment of periodontal diseases in school-going children

Acronym

Eff-Vit-Per-Kids

Study objectives

Appropriate supplementation with Vitamin C and Vitamin D improves periodontal health in school-going children by reducing inflammation, enhancing immune response, and promoting tissue healing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/01/2019, Institutional Review Board, Faculty of Allied Health Sciences, The University of Lahore, 1-Km, Defence Road Campus, Off Bhobatian Chowk, Lahore, 54000, Pakistan, +924235322501-12, info@uol.edu.pk, ref: IRB-UOL-FAHS/83511/2019

Study design

Non-randomized study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

School, University/medical school/dental school

Study type(s)

Screening, Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Periodontal disease

Interventions

Cross-sectional phase 1 for baseline assessment followed by interventional phase 2 with modified RCT protocol among two groups (Group A with non-deficient children and group B with deficient children) to allow for intervention to only be given to children who were deficient, blinding done by switching of examiners between baseline assessment, intervention and follow-up examination.

First visit (baseline): each child (and a parent) answers a short questionnaire about home dental habits, demographics, and vitamin deficiency and then has a dental checkup.

Group allocation:

Group A (control): professional ultrasonic scaling + dental hygiene advice.

Group B (vitamin C and D deficient group): the same scaling and advice plus vitamin C and D supplements.

Follow-up visits: after 4 weeks and again after 8 weeks the dentists re-measure the Gingival Index and pocket depth. All children receive the same brushing advice at every visit.

Intervention Type

Supplement

Primary outcome measure

Gingival health measured using the Silness-Loe Gingival Index (GI) at baseline, 4 and 8 weeks

Secondary outcome measures

Probing depth measured using a Williams probe on a periodontal chart at baseline, 4 and 8 weeks

Overall study start date

08/09/2021

Completion date

05/02/2024

Eligibility

Key inclusion criteria

- 1. School-going children
- 2. No systemic diseases
- 3. Not taking antibiotic therapy
- 4. 4-12 years of age

Participant type(s)

Learner/student

Age group

Child

Lower age limit

4 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

306

Total final enrolment

200

Key exclusion criteria

- 1. Participants with systemic disease like diabetes or otherwise immunocompromised
- 2. Participants taking antibiotics

Date of first enrolment

01/10/2021

Date of final enrolment

03/11/2021

Locations

Countries of recruitment

Pakistan

Study participating centre University Dental Hospital, The University of Lahore University Dental Hospital, Sultan Town

Lahore Pakistan 54000

Sponsor information

Organisation

University of Lahore

Sponsor details

1 – KM Defence Road Lahore Pakistan 54000 +92 (0)42 111865865 info@uol.edu.pk

Sponsor type

University/education

Website

https://uol.edu.pk

ROR

https://ror.org/051jrjw38

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Arooj ul Hassan (aroojch678@hotmail.com)

IPD sharing plan summary

Available on request