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Can vitamin supplements help school children in healing gum diseases?

Submission date
31/05/2025

Recruitment status
No longer recruiting

Registration date
05/08/2025

Overall study status
Completed

Last Edited
13/06/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Screening, Treatment

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.

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Intervention Type
Supplement

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

Key secondary outcome(s))
Probing depth measured using a Williams probe on a periodontal chart at baseline, 4 and 8 weeks

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 years

Upper age limit
12 years

Sex
All

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

ROR
https://ror.org/051jrjw38

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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