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The effect of dental and periodontal treatment on blood sugar control in children and teenagers with type 1 diabetes

Submission date
29/09/2026

Recruitment status
Recruiting

Registration date
06/10/2026

Overall study status
Ongoing

Last Edited
06/10/2026

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
Type 1 diabetes is a long-term condition that affects blood sugar control and requires ongoing treatment. Children and young people with type 1 diabetes are at increased risk of dental and gum disease. Research in adults suggests that improving oral health may help improve blood sugar control, but this has not been adequately studied in children and adolescents. This study aims to assess whether dental and periodontal treatment can improve glycaemic control and oral health outcomes in children and young people with type 1 diabetes.

Who can participate?
Children and young people aged 6 to 18 years with type 1 diabetes and evidence of dental caries and/or periodontal disease.

What does the study involve?
Participants are randomly allocated to either an immediate-treatment group or a delayed-treatment group. Those in the immediate-treatment group receive dental and periodontal treatment shortly after enrolment, while those in the delayed-treatment group receive the same treatment after a 3-month waiting period. Treatment may include preventive advice, professional cleaning, restorative dental care and other routine dental procedures as required. Researchers assess oral health and blood sugar control at baseline and follow-up visits. The study includes an internal pilot phase to assess recruitment, retention and treatment delivery before progressing to the main trial.

What are the possible benefits and risks of participating?
Participants may benefit from improved oral health and may also experience improvements in blood sugar control. The information gained may help improve future care for children and young people with type 1 diabetes. Risks are expected to be similar to those associated with routine dental treatment and may include temporary discomfort during examinations or treatment procedures.

Where is the study run from?
The study is coordinated by King Saud University, Riyadh, Saudi Arabia, and is being conducted at study sites in Saudi Arabia.

When is the study starting and how long is it expected to run for?
May 2025. Recruitment is expected to continue until 31 December 2027, and the overall study completion date is 30 April 2028.

Who is funding the study?
The study is investigator initiated and funded.

Who is the main contact?
Dr Ahlam Alotaibi, King Saud University, Saudi Arabia, aalotaibi38@ksu.edu.sa

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
The effect of dental/periodontal treatment on glycemic control in children and adolescents with type 1 diabetes mellitus: a randomized controlled trial with an internal vanguard (pilot) phase

Study objectives
To determine whether dental/periodontal treatment improves glycemic control (HbA1c and time in target glucose range) in children and adolescents with type 1 diabetes mellitus (T1DM) and coexisting dental or periodontal disease, compared with delayed treatment. The trial began with an internal vanguard (pilot) phase to establish operational feasibility (recruitment, retention, and intervention-delivery rates ≥80%) before proceeding to full-scale, multicenter enrollment.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 11/12/2023, King Abdullah bin Abdulaziz University Hospital IRB Committee (Airport Road, Riyadh, 11671, with a P.O. Box of 84428, Saudi Arabia; +966118220000; irb@kaauh.edu.sa), ref: HA-01-R-104

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Type 1 diabetes mellitus with coexisting dental caries, gingivitis, or chronic apical periodontitis, in children and adolescents

Interventions
Intervention arm: dental/periodontal treatment (preventive, restorative, and radiological assessments as clinically indicated) at the pediatric dental clinic, standardized treatment plan, expected completion within 1 month.
Comparator arm: delayed treatment (wait-list control) — participants wait 3 months, then receive the same standardized treatment as the intervention arm.
Randomization: 1:1, blocked and stratified by baseline HbA1c (<7%, 7–9%, >9%), allocation generated via REDCap.
Follow-up: participants assessed at baseline and again 3 months after finishing their respective treatment period.

Intervention Type
Other

Primary outcome(s)
1. Feasibility: recruitment, retention and intervention-delivery rates measured using study data collection, assessed against three prespecified progression criteria (target at least 80% each), at the end of the internal pilot phase

2. Main trial primary outcome: Glycaemic outcomes: HbA1c; percentage of time in target glucose range (70–180 mg/dL) measured using laboratory serum HbA1c assay and continuous glucose monitoring (CGM) data, at baseline and 3 months following completion of treatment

Key secondary outcome(s)
1. Plaque Index (PI), Bleeding on Probing (BOP), Probing Pocket Depth (PPD) and Gingival Index (GI) measured using a dental probe at baseline and 3 months following completion of treatment

2. Dental risk measured using the American Academy of Pediatric Dentistry (AAPD) Caries-risk Assessment Tool (CAT) for patients aged 6 years and older, completed by a pediatric dentist, at baseline and 3 months following completion of treatment

3. Relationship between change in glycemic control and change in dental indices and dental risk measured using Laboratory serum HbA1c assay; CGM data; dental examination; AAPD CAT at baseline and 3 months following completion of treatment

4. Cost of trial participation is measured using a standardized cost-collection form recording: expense incurred coming to the hospital (SAR); parental work hours lost; child school hours lost; endocrinologist time (minutes); dentist (physician) time; oral hygiene time; radiology type; consumables used; local anesthesia use; general anesthesia use; fluoride application; fissure sealant; and dental diagnosis, at the screening and treatment visits of the main RCT, measured using a standardized cost-collection form recording at the screening and treatment visits of the main RCT

Completion date
30/04/2028

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of type 1 diabetes mellitus
2. Age 6–18 years
3. Diagnosis of relevant dental or periodontal disease (dental caries, gingivitis, or chronic apical periodontitis)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
6 Years

Upper age limit
18 Years

Sex
All

Total final enrolment
20

Key exclusion criteria

1. Systemic inflammatory disease
2. Congenital or genetic dental abnormalities
3. Ongoing orthodontic treatment
4. Chronic use of corticosteroids or antibiotics

Date of first enrolment
01/05/2025

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Saudi Arabia

Sponsor information

Organisation
King Abdullah Bin Abdulaziz University Hospital

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data underlying the results will be made available on reasonable request to the corresponding author (Ahlam Alotaibi, aalotaibi38@ksu.edu.sa), following publication, for the purpose of academic collaboration or meta-analysis, subject to institutional and ethics committee approval.

IPD sharing plan summary
Available on request