ISRCTN89652137 https://doi.org/10.1186/ISRCTN89652137

Holistic approach to investigate dental caries in diabetes patients

Submission date 13/09/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/09/2019	**Overall study status** Completed	
Last Edited 26/09/2019	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims:
Diabetes mellitus affects almost 4 million people in the UK, and by 2025, it is estimated that 5 million people will have diabetes. Diabetes can cause oral health problems including dry mouth, tooth decay, gum problems, tongue sores and mouth ulcers. This study aims to investigate factors that might promote or reduce dental decay in patients with or without type 2 diabetes, including oral hygiene behaviour, saliva properties, bacteria found in the mouth, blood glucose levels and vitamin D levels.

Who can participate?
Non-diabetic adults and adults with type 2 diabetes

What does the study involve?
Participants will fill in a questionnaire on their lifestyle and how they look after their teeth. They will also provide a saliva (spit) sample. A dentist will examine their teeth, including taking X-rays if needed, and will take a sample of dental plaque. A nurse will take a blood sample. All participants will receive instruction on oral hygiene along with a free toothbrush and toothpaste.

What are the possible benefits and risks of participating?
Participants will benefit from an examination of their saliva and teeth conditions. They will also be able to verify their blood glucose, vitamin D level and if they are suffering from hyposalivation (reduced saliva, leading to a dry mouth). Teeth will be examined for tooth decay. In addition, the participants will be assessed on their risk of developing new decay. Finally, oral hygiene (cleaning the teeth and mouth) instructions with a free toothpaste and toothbrush will be provided.

Where is the study run from?
Bart's Health NHS Trust hospitals, Royal London Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2018 to September 2019

Who is funding the study?
This study is part of a PhD study which is fully funded by the Saudi Arabia Cultural Bureau in Britain (SACB). Part of the funding was awarded for this clinical project by the Novo Nordisk UK Research Foundation.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Holistic approach to investigate protective and risk factors for dental caries in patients with or without diabetes type 2

Study objectives
Primary outcome: The extent of dental caries in participants either with diabetes type 2 or without diabetes type 2.

Holistic investigation of most potential protective and risk factors of dental caries among individuals with diabetes type 2 by the employment of clinical, salivary, Vitamin D, blood and microbial (dental plaque) analyses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational case-control study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Dental caries

Interventions
All the following assessments will be carried out:
1. Medical and dental history
2. Questionnaire of relevant protective and risk factors for dental caries
3. Unstimulated Whole Saliva tests (USWS) to measure flow rate, pH, buffer capacity and Spinnbarkeit
4. Stimulated whole saliva sample collecting for later saliva physical and chemical analyses (salivary osmolality, total proteins, total antioxidant capacity, nitrate oxide and saliva electrolytes (calcium, phosphate, sodium, potassium, fluoride and zinc)
5. A blood sample will be obtained by a registered nurse to do a glycated haemoglobin test (HbA1c) to measure glucose control and Vitamin D level
6. Dental plaque scoring
7. Supragingival plaque sample collecting for later analyses or total bacterial load, Streptococcus mutans count and Lactobacillus count

A further assessment will follow supragingival and subgingival debridement (if required) using ultrasonic scaler with polishing using the prophylaxis paste (NUPRO DENTSPLY, Germany).
8. Dental caries (coronal and root) examination via ICDAS-II index and root severity index
9. Dental caries detection using laser fluorescence evaluator (SoproLife ®, Acteon, La Ciotat, France)
10. Dental caries risk assessment by CAMBRA model
11. Oral hygiene instructions with a free toothpaste and toothbrush

Intervention Type
Other

Primary outcome(s)

Extent of dental caries assessed using the International Caries Detection and Assessment System (ICDAS) and severity index during the assessment process.

Key secondary outcome(s))
1. Dental caries risk levels measured using Caries Management by Risk Assessment (CAMBRA) during the examination stage
2. Streptococcus mutans, Lactobacillus bacteria and total bacterial load in supragingival plaque measured using a real-time PCR assay
3. Unstimulated saliva flow rate measured using saliva weight
4. Saliva pH and buffer capacity using the saliva-check buffer testing mat kit
5. Saliva Spinnbarkeit (fibrosity) measured using the NevaMeter device
6. Stimulated whole saliva, total proteins, total antioxidant capacity and nitrate oxide measured using assay kit where the reaction is measured by spectrophotometer
7. Saliva electrolytes measured using Ion Selective Electrode (ISE) and Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES)
8. Blood HbA1c and vitamin D levels measured using specific assay kits

Completion date
11/09/2022

Eligibility

Key inclusion criteria
1. Participants who are male or female ≥18 years of age
2. For the test group, they have been diagnosed with type 2 diabetes
3. For the control group, participants who are not diagnosed with type 2 diabetes
4. Participants having minimum one natural tooth
5. Capable of giving informed consent
6. Ability to understand and speak English
7. Able and willing to comply with all trial requirements
8. Not participating in another dental trial
9. Not diagnosed with cognitive defect due to mental illness, depression, Alzheimer's disease, or dementia
10. No antibiotic, no steroidal and/or non-steroidal anti-inflammatory medication used during the last 3 weeks
11. Not pregnant or breastfeeding
12. Not in another dental study testing different dental products during the previous 3 months and during the study period
13. Not currently taking Vitamin D supplements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. Participants who are edentulous
2. Cognitive defect due to mental illness, depression, Alzheimer's disease, or dementia
3. The presence of any hard or soft tissue tumours in the oral cavity
4. Patients undergoing chemo and/or radiation therapy
5. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant’s ability to participate in the trial
6. Any condition, which in the opinion of the investigator, would preclude participation by the subject (such as cross-infection control risk)
7. Participants who are prescribed long-term systemic antibiotics
8. Participants who are pregnant or breastfeeding
9. Participations who are in another dental study testing different dental products during the previous three months and during the study period
10. Participants who had additional fluoride treatment in the past 6/3 months
11. Participants who are prescribed to use high fluoridated toothpaste
12. Participants who are currently taking Vitamin D supplements

Date of first enrolment
16/12/2019

Date of final enrolment
11/04/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Barts Health NHS Trust/The Royal London Dental Hospital
The Royal London Hospital
Whitechapel Rd
Whitechapel
London
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Sponsor information

Organisation
Queen Mary University of London (UK)

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Research organisation

Funder Name
Novo Nordisk UK Research Foundation

Alternative Name(s)
Novo Nordisk UK Research Foundation (NNUKRF), The Novo Nordisk UK Research Foundation, ovo Nordisk Research Foundation UK, NNUKRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Saudi Arabia Cultural Bureau in London

Alternative Name(s)
Royal Embassy of Saudi Arabia Cultural Bureau in London, Royal Embassy of Saudi Arabia - Cultural Bureau in London, Royal Embassy of Saudi Arabia Cultural Bureau, SACB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes