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Diabetes, high blood pressure and COVID-19 exposure screening in a dental setting

Submission date
28/04/2021

Recruitment status
No longer recruiting

Registration date
25/05/2021

Overall study status
Completed

Last Edited
25/05/2021

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
On a global level, there is an astonishingly rapid rise in the prevalence of non-communicable diseases (NCDs). NCDs are defined as diseases that are non-transmissible amongst individuals. Two of the most common diseases being diabetes and high blood pressure (hypertension), in which the rate of undiagnosed cases is continually rising. Recent figures have estimated that between one to five million individuals remain undiagnosed for diabetes and high blood pressure in the UK, as both rarely cause symptoms in their early stages. Both of these conditions are major risk factors for coronavirus disease 2019 (COVID-19) severity and a majority of global COVID-19 deaths were related to these two conditions, therefore prevention and early detection of these is key. Furthermore, emerging evidence has shown that exposure to COVID-19 may increase the risk of future developments of other illnesses and health complications. Dental professionals have access to different cohorts of the population and members of the public may be more likely to visit their dentist than their general medical practitioner. Therefore, dentists may be in a fortunate position to access patients that are not seeking medical services elsewhere and ideally risk assess, offer preventative advice and screen for conditions such as diabetes and high blood pressure.
Therefore, the dental clinic may be a particularly unique and unrecognised opportunity for screening for such conditions, as they share common risk factors with oral diseases like gum disease (periodontitis). There is well-established evidence linking diabetes with periodontitis and growing evidence supporting the link with high blood pressure. Consequently, there is merit for opportunistic screening of diabetes and high blood pressure in patients in a dental clinic, which could prove to be extremely valuable in early detection and intervention.
The main aims are to investigate the prevalence of elevated HbA1c, elevated blood pressure and COVID-19 exposure in patients in a dental clinic compared to the national average in the UK population.

Who can participate?
Participants must be scheduled to attend the Restorative new patient clinic at the Royal National Ear, Nose and Throat (ENT) and Eastman Dental Hospitals or those allocated to begin treatment and be at least 18 years of age, in good general health, with a minimum of 20 teeth.

What does the study involve?
Assessment of eligibility to participate will take place at visit 1. Following this, visit 2 (if required) will entail the data collection including a 'finger prick' blood test, blood pressure measurements, height and weight measurements in order to measure body mass index (BMI), and COVID-19 screening. If time permits, visit 1 and visit 2 can be performed together in the same visit. If deemed appropriate, a letter shall be sent to the GP for further investigation dependent upon the blood test and blood pressure measurements.

Visit 1:
This visit will be the appointment in the new patient clinic or the first treatment visits and during this appointment eligibility to participate will be assessed. Potential participants will have the opportunity to ask questions to the study staff.

Visit 2:
If an individual wishes to take part, they will be asked to sign two copies of the consent form. Data to be collected will include the 'finger prick' blood test (which will include a droplet of blood which is then immediately disposed of), blood pressure measurements, height and weight measurements in order to measure body mass index (BMI), and COVID-19 screening. COVID-19 screening involves antigen and antibody testing. Antigen testing involves a nose and throat swab whereas antibody testing involves a 'finger prick' droplet of blood which is then disposed of.

As noted above, if time permits visit 1 and visit 2 can be combined and performed together as one visit.

What are the possible benefits and risks of participating?
The benefits include screening measurements for the level of blood sugar, blood pressure control and COVID-19. This may potentially highlight levels of pre-diabetes/diabetes and/or pre-hypertension/hypertension in which further investigation may be required with the GP to facilitate the opportunity of addressing this as appropriate. The study measurements are all minimally invasive and carry a low risk of pain, bruising, bleeding and infection.

Where is the study run from?
The Royal National ENT and Eastman Dental Hospitals (UK)

When is the study starting and how long is it expected to run for?
July 2020 to May 2024

Who is funding the study?
BHR Pharmaceuticals Limited (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
286856

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48072, IRAS 286856

Study information

Scientific Title
Diabetes, hypertension and COVID-19 exposure screening in a tertiary care dental setting (DIHSCO)

Acronym
DIHSCO

Study objectives
The prevalence of adults presenting with elevated blood pressure and elevated HbA1c is higher than the national UK average.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/03/2021, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHS Blood and Transplant Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), REC ref: 21/YH/0015

Study design
Observational; Design type: Cross-sectional

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Diabetes, hypertension, COVID-19 (SARS-CoV-2 infection)

Interventions
This is a single-centre, observational prospective study with two groups for secondary outcome analysis: participants with an intact periodontium and those with periodontitis.

Clinical assessments and sample collections will be performed at the same time points for all participants. The study participants will be recruited from those individuals attending the Eastman Dental Hospital and/or Institute presenting with periodontitis to the postgraduate Periodontology clinic and those with a healthy periodontium on other postgraduate clinics.

Following the baseline visit with clinical assessment, qualifying participants will be consented and scheduled for a second visit for sample collection (If time permits, visit 1 and visit 2 can be performed on the same date). Participants identified as having a high HbA1c level (>42 mmol /mol), high blood pressure (>130/85 mmHg) and/or COVID-19 positive antibody or antigen test will be given a written letter addressed to their general medical practitioner (GP) stating the findings. This letter will request for their GP to follow up the patient, carry out further investigation and manage as they see necessary for definitive diagnosis. No further follow-up will be required.

The study will recruit 1056 participants, based upon a sample size calculation.

Prior to Visit 1:
All patients scheduled to attend the Restorative new patient clinic will be mailed a participant information sheet and presented with the details of the study prior to attending the new patient clinic. This information will be mailed attached to their clinical appointment letter and medical history questionnaire. The mailing will be organised by the Eastman Central Registry for Appointments (ECRA). They will be allowed adequate time to consider their participation in the study and willingness to participate is confirmed through written informed consent, taken at the clinic appointment.

Visit 1 (Restorative Division (Periodontic, Endodontic, Prosthodontic) new patient clinics):
1. Receipt of information sheet confirmed
2. COVID-19 triaging questions including history of COVID-19 symptoms, previous testing, contact with COVID-19 positive individuals and shielding
3. Demographic data obtained
4. Medical and dental history obtained
5. Study Eligibility based on inclusion and exclusion criteria based on initial clinical examination findings

Visit 2:
1. If time permits, visit 1 and visit 2 can be performed on the same date
2. Informed Consent
3. Clinical periodontal assessment
4. Height and weight measurement (to calculate BMI)
5. Glycated haemoglobin (HbA1c) and lipid profile measure with “finger-prick” point-of-care testing
6. Upper arm blood pressure (brachial artery) measured on multiple occasions
7. COVID-19 antibody test using "finger-prick" blood test
8. COVID-19 antigen test using nose and throat swab
9. Individuals with elevated HbA1c levels measured >42 mmol/mol and/or systolic/diastolic blood pressure measured >130/85 mmHg and/or COVID-19 antibody or antigen-positive patients will be given a standardised letter addressed to their GP for further investigation, definitive diagnosis and management as necessary. A copy will be sent to the patients referring general dentist.

Intervention Type
Other

Primary outcome measure
1. Prevalence of elevated HbA1c in the study population, measured using a point of care test (POCT) Quo-Test Analyser at baseline
2. Prevalence of elevated blood pressure in the study population, measured using an automated blood pressure machine at baseline
3. Prevalence of positive tests results for COVID-19 antigen and antibody tests in the study sample, measured with a BioCredit COVID-19 AG antigen test and a COVID-19 antibody test at baseline

Secondary outcome measures
1. Prevalence of elevated HbA1c in periodontitis patients compared to patients with an intact periodontium, measured using a point of care test (POCT) Quo-Test Analyser at baseline
2. Prevalence of elevated blood pressure in periodontitis patients compared to patients with an intact periodontium, measured using an automated blood pressure machine at baseline
3. Prevalence of elevated lipid profiles in the study population, measured with the Cardiocheck PA blood analyser at baseline
4. Prevalence of elevated lipid profiles in periodontitis patients compared to patients with an intact periodontium, measured with the Cardiocheck PA blood analyser at baseline
5. Prevalence of positive COVID-19 antigen or antibody test results in periodontitis patients compared to patients with an intact periodontium, measured with a BioCredit COVID-19 AG antigen test and a COVID-19 antibody test at baseline

Overall study start date

01/07/2020

Completion date
24/05/2024

Eligibility

Key inclusion criteria
1. At least 18 years of age and in good general health
2. A minimum of 20 teeth (not including dental implants)
3. Must voluntarily agree to sign the consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1056; UK Sample Size: 1056

Key exclusion criteria
1. Uncontrolled or currently undergoing treatment for systemic medical conditions (excluding diabetes and hypertension) including, but not limited to hepatic disease, renal disease, transmittable diseases, cancer, or HIV
2. On chronic treatment (defined as 2 weeks or more) of antibiotic, anti-inflammatory or anticoagulant therapy during the month preceding the baseline assessment
3. Self-reported pregnancy or lactation (due to possible oral tissue changes related to pregnancy and breastfeeding which can affect the interpretation of study results)
4. Concurrently participating in other clinical studies

Date of first enrolment
24/05/2021

Date of final enrolment
24/05/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
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Sponsor information

Organisation
University College London

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Sponsor type
University/education

Website
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ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
BHR Pharmaceuticals Limited

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal in late 2024.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
Datasets are not expected to be made available due to intellectual property ownership by the investigators and the university.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.1	25/02/2021	25/05/2021	No	Yes
HRA research summary			28/06/2023	No	No