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A study to collect data of patients who were diagnosed with periodontal disease

Submission date
18/08/2023

Recruitment status
No longer recruiting

Registration date
23/08/2023

Overall study status
Ongoing

Last Edited
05/09/2025

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
Patients with periodontitis suffer from gum recession whereby the gum moves down to expose more of the tooth and the tooth root. It is important to be able to measure gum recession accurately as it, together with a measurement of the pockets that develop around teeth which are affected by periodontitis, tells the dentist how badly affected the tooth is. This study is designed to collect data over a period of up to 2 years from patients that are diagnosed with periodontitis and receive treatment for it as part of standard care. Researchers want to see how well a 3D scan of the teeth and gums can track gum recession and recovery and compare the scans with the traditional ways in which these changes are measured and monitored in patient records such as by periodontal charting, radiographs, and intra-oral photos.
The main aim of this study is to track gum recession by standard measurements made by the clinician following a visual inspection of the teeth and using the images captured by the intra-oral 3D scanner in individuals with periodontitis throughout their course of periodontal therapy and maintenance. The researchers also want to examine the other changes that occur around the teeth such as bleeding and tooth mobility that are recorded as part of standard care.

Who can participate?
Adults aged 18 years and older with periodontal disease and a minimum of 20 of their own teeth

What does the study involve?
The study involves attending the dental clinic for the periodontal treatment that has been identified as part of standard dental care and for the associated supportive therapy appointments after the initial treatment. For the study, at these appointments scheduled as part of the standard clinical treatment for periodontal disease, the study team will use an intra-oral scanner to take a pictorial image of the mouth and measure the health of the gums using standard indices. Participants will be in the study for up to 2 years as their course of treatment /supportive therapy is completed.

What are the possible benefits and risks of participating?
There are no direct benefits for participants, but the information gained from the study may

help improve the assessment of gum recession and recovery in patients in the future. There may be some minor discomfort during the scanning process, and very rarely a soft electric shock may be felt.

Where is the study run from?
Bristol Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2020 to September 2026

Who is funding the study?
Align Technology (USA)

Who is the main contact?
Prof. Nicola West, n.x.west@bristol.ac.uk

Contact information

Type(s)
Principal Investigator

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number
288321

ClinicalTrials.gov number

Secondary identifying numbers
iT-06-2020

Study information

Scientific Title
Periodontal patients 3D scan to track gingival recession

Study objectives
Gingival recession assessments measured from 3D scans will correlate with manual gingival recession measurements

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/10/2021, Yorkshire & The Humber - Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8141; leedseast.rec@hra.nhs.uk), ref: 21/YH/0201

Study design
Single-centre longitudinal case-control study

Primary study design
Observational

Secondary study design
Longitudinal case-control study

Study setting(s)
Dental clinic

Study type(s)
Diagnostic, Screening

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

Health condition(s) or problem(s) studied
Diagnosis of extent of gingival recession in patients with periodontal disease

Interventions
There is no randomisation, all participants receive the same intervention, a 3D intra oral scan. Their gingivial recession will be measured manually and from the images captured on the scan. Participants will be in the study for up to 2 years, 3D scans being taken and their gingival recession measured manually and from the scan at their initial scheduled peridontal appointment and subsequent supportive therapy sessions.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
iTero Element 5D imaging system

Primary outcome measure
Gum recession: the distance between the cemento-enamel junction to the lowest point of the gingiva, measured in millimetres using a UNC-15 periodontal probe at each study visit, expected to be determined at baseline, 3, 6, 9, 12 and 24 months

Secondary outcome measures
1. Pocket probing depth, measured in millimetres using a UNC-15 periodontal probe
2. Presence or absence of dental plaque at four sites per tooth, measured using the O'Leary plaque index
3. Presence or absence of bleeding on probing (six sites probed per tooth), measured according to the methods of Ainamo and Bay, using a periodontal probe which is applied to the base of the pocket
These are all expected to be measured at baseline, 3, 6, 9, 12 and 24 months

Overall study start date
08/06/2020

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Aged 18 years old and above with permanent teeth
2. Patients that are diagnosed with periodontal diseases (gingivitis, periodontitis) and are undergoing treatment to manage the condition
3. Have at least 20 natural teeth
4. Be willing and physically able to undergo all study procedures
5. Be willing and competent (verbally and cognitively) to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Obvious signs of untreated caries, which in the opinion of the Study Dentist will affect the scientific validity of the study
2. Current orthodontic treatment
3. Participants who have been diagnosed with epilepsy
4. Current participation in any other clinical trials
5. Any participant who, in the reasonable judgement of the investigator, should not participate in the study
6. An immediate employee of the sponsor or the research team conducting the study. Employees of the Sponsor or research site not associated with the research team are eligible to participate

Date of first enrolment
17/08/2022

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Rhiwbina Dental Surgery
25-27 Heol y Deri
Cardiff

United Kingdom
CF14 6HB

Sponsor information

Organisation
University of Bristol

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Sponsor type
University/education

Website
https://www.bristol.ac.uk/red/research-governance/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Industry

Funder Name
Align Technology

Results and Publications

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

Intention to publish date
31/07/2027

Individual participant data (IPD) sharing plan

The anonymised participant data (clinical scores and questionnaire) generated during the current study will be shared once the data has been published and will be stored in the publicly available University of Bristol Research Data Repository (https://data.bris.ac.uk/data/) with a DOI maintained for a minimum of 20 years. Data will be made available as restricted access to bonafide researchers who provide a methodologically sound proposal and evidence of ethical approval (if required), subject to the agreement of the University of Bristol Data Access Committee for analysis to achieve aims in the approved proposal. Proposals will also be subject to the prior written consent of the funder.

IPD sharing plan summary

Stored in publicly available repository