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A multi-site observational study looking at the risk factors associated with tooth sensitivity, receding gums and tooth wear

Submission date
09/10/2018

Recruitment status
No longer recruiting

Registration date
29/10/2018

Overall study status
Completed

Last Edited
10/10/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims

Tooth sensitivity (also known as dentine hypersensitivity (DH)) can be a painful condition, which happens when an area of the tooth at the gum edge becomes exposed. It is thought that the short, sharp pain associated with DH is due to stimuli such hot, cold, touch, sweet and/or sour travelling down open dentine tubules (tiny channels) within the tooth and reaching the tooth's nerve and causing pain. Several risk factors have been identified for tooth sensitivity including receding gums, gum disease (periodontitis) and its treatment, and erosive tooth wear of tooth enamel. In 2011, a study was conducted across general dental practices and University teaching hospitals in Europe to investigate the relationship between tooth sensitivity, erosive tooth wear and gum disease in the causes of non-carious cervical lesions. These lesions are the loss of hard dental tissue between the crown and root of a tooth, usually on the cheek side of the teeth, resulting in a grooved or wedge-shaped area of missing tooth structure The results from the study showed that tooth sensitivity was associated with erosive tooth wear and both were also significantly associated with exposure of teeth to acids, in particular sports drinks and fruit. Several unexpected results also arose including tooth sensitivity inversely correlating with wobbly teeth and a positive association with snoring. The use of an electric toothbrush was significantly associated with erosive/abrasive tooth wear, although a similar correlation was not detected with tooth sensitivity. The differences in the prevalence of tooth sensitivity and erosive tooth wear observed between the participating countries may reflect variations in customs and practices, such as the frequency of use of an electric toothbrush.

The aim of this new study is to determine the prevalence of recession (receding gums), tooth wear and tooth sensitivity and the risk factors associated with these conditions in healthy adults aged 18 attending general dental practices and University teaching hospitals in 7 European countries. This study will supplement the data already collected and build on the 2011 findings. Furthermore, the study will aim to provide more comprehensive data from a larger number of participants per country so that country specific habits can be better correlated with prevalence figures, allowing for data to be analysed by country as well as across all countries represented in the study. The data collected will provide a better insight into risk factors for recession (receding

gums), tooth wear, tooth sensitivity and periodontal (gum) disease. It will also help to improve the understanding of how the risk factors interact and how the presence of single or multiple risk factors relate to prevalence of the conditions.

Who can participate?
Healthy adults with at least 10 teeth who are attending a general dental practice for an appointment with a dental professional

What does the study involve?
Participants will be asked to complete a questionnaire relating to tooth sensitivity, tooth wear and periodontal health. Following completion of the questionnaire, the participants will also undergo a standardised oral clinical examination, which will include an examination of tooth wear, hypersensitivity, gum recession.
Each study dentist will request consent from participants to take photographic images of their mouth when required. At regular intervals during the study, the research dentists will be required to submit photographs to the central coordinating research centre to confirm ongoing calibration with the clinical assessments being performed. The photographs will be identified by participant number/country code and site number and will only include an image of the oral area.

What are the possible benefits and risks of participating?
There will be no immediate benefit for those participating in this study, but it is anticipated that the results of the study will provide up to date information for dentists about the extent of and risk factors associated with the conditions investigated, and influence future oral health strategy thus benefiting patients in the future.
The clinical exam will be undertaken by a qualified dentist who has received additional training in the clinical scores that are to be recorded. The conditions will be scored as they would be in a standard clinical exam, however the tests for dentine hypersensitivity could cause the patient some discomfort. Dentine hypersensitivity pain, however is generally short lived, and the potential that this test may cause pain will be indicated on the participant information sheet. The study will add some time to the appointments of patients in the main study, but this will be explained to the patient when they are approached to take part and they can decline participation if they do not have time to spare without this affecting their care in any way.

Where is the study run from?
The study is run from the Clinical Trials Unit, Bristol Dental School & Hospital (UK) and is also being set up to run through 6 other European countries – Germany, Ireland, Italy, Portugal, Spain and Switzerland.

When is the study starting and how long is it expected to run for?
January 2016 to June 2022

Who is funding the study?
GlaxoSmithKline (UK)

Who is the main contact?
Professor Nicola West
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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RED ref 2915

Study information

Scientific Title
Recession, dentine hypersensitivity, tooth wear and associated risk factors: An observational, cross-sectional multi-centre epidemiological study

Acronym
Project Meribel

Study objectives
To determine the prevalence of recession, tooth wear and dentine hypersensitivity and the risk factors associated with these conditions in adults aged 18 and over, attending general dental practices in 7 European countries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey REC, 24/04/2018, REC ref: 18/LO/0664

Study design
Observational multi-centre cross-sectional epidemiological study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Other

Study type(s)
Prevention

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
Dentine hypersensitivity
Tooth wear
Recession
Clinical loss of attachment
Oral hygiene habits
Dietary habits

Interventions
To complete the study, the participants will need to attend the study site for 1 visit only. This appointment will last approximately 30 minutes and will comprise of informed consent, eligibility, completion of a questionnaire and an oral examination. Participants who provide written informed consent to participate in the study and fulfil the inclusion and exclusion criteria, will be asked to complete a questionnaire relating to tooth sensitivity, tooth wear and periodontal health. The questionnaire will be completed under the supervision of a designated member of the study team, who will be available to answer any questions the participant may have. Completion of the questionnaire takes 5–10 minutes. Following completion of the questionnaire, the participants will also undergo a standardised clinical oral examination with a trained and calibrated research dentist. The oral examination will take 20 minutes and will look at tooth wear, tooth sensitivity and gum health.

Intervention Type
Mixed

Primary outcome measure
To determine the prevalence of recession, tooth wear and dentine hypersensitivity and the risk factors associated with these conditions in adults aged 18 and over, attending general dental practices in 7 European countries.
To do so, the following factors will be assessed at the study visit:
1. Clinical data about tooth wear, evaluated using the BEWE Index on an ordinal scale ranging from 0 to 3
2. Clinical data about tooth sensitivity, evaluated using the:
2.1. Schiff index (ordinal scale, 0 to 3)
2.2. Hypersensitivity index (binary, 0 = no, 1=yes on stimulus)
3. Clinical data about the health of the gums, evaluated using:
3.1. Periodontal Screening and Recording (PSR/BPE)
3.2. Recording periodontal conditional from a clinical perspective as ‘healthy / gingivitis /

periodontitis / treated periodontitis'
3.3. Largest recession defect (mm) buccally and palatally/lingually
3.4. Depth of periodontal pocket at site of recession defect (mm) (recorded mid-buccal/palatal if no recession present)
3.5. Presence or absence of bleeding gums
3.6. um phenotype evaluated as thin or thick
4. Clinical data on cervical localisation of tooth wear and recession, measured using an index scored from 0 to 3.

Secondary outcome measures
The following are assessed at the end of the study by a statistical analysis of all data collected:
1. Changes in prevalence and risk factors between the two studies (this study and Escarcel 2011 study) for the 18-36 age group
2. Changes in prevalence and risk factors between 18-35 cohort in Escarcel 2011 study and 25-42 cohort in this study
3. Relationship between patient perception of their oral health and dentition and the dentist recorded clinical indices
4. Relationship between risk factors and the prevalence of each of the three conditions under study across all countries and per country
5. Impact of dentine hypersensitivity on quality of life

Overall study start date
01/01/2016

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Healthy participants of either gender who are attending a general dental practice for an appointment with a dental professional
2. Aged 18 years or over
3. Understand and are willing, able and likely to comply with all study procedures and restrictions
4. Accept the form of the study and sign a declaration of informed consent
5. In good health (see exclusion criteria below)
6. Have a minimum of 10 teeth not including implants or teeth with crowns or bridges

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
We shall use reasonable endeavours to recruit approximately 700 participants from each of 7 countries, a total sample size of 4900. Each centre will continue to approach ostensibly eligible participants until the quota of eligible participants is achieved. Recruitment will be guided by age and gender stratifications. Recruited participants will be divided into the following age ranges: 18-27, 28-37, 38-47, 48-57, 58+. The aim will be to recruit approximately 70 males and 70 females per age stratification.

Total final enrolment
3551

Key exclusion criteria
1. Incapable of responding to the questions
2. 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.
3. Women known to be pregnant
4. Currently using maxillary or mandibular orthodontic appliances
5. Used analgesic (pain relieving) drugs or had used a topical analgesic in the preceding 24 hours
6. Required antibiotic cover (following infectious endocarditis, using prosthetic cardiac valves)
7. Having pathology – haemophilia, using anti-coagulants (including plaque anti-aggregants)
8. Anyone who in the investigators opinion is not suitable to take part in the study

Date of first enrolment
16/10/2018

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

Germany

Ireland

Italy

Portugal

Spain

Switzerland

United Kingdom

Study participating centre

The Dental Clinical Trials Unit,
Bristol Dental School and Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY

Sponsor information

Organisation
University of Bristol

Sponsor details
Research and Enterprise Development
1 Cathedral Square
Bristol
England
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BS1 5DD

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Not defined

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

1. Peer reviewed journal to publish papers from the study
2. Presentation at a dental research conference

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The anonymised participant data (clinical scores and questionnaire data) 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 (GSK).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		22/09/2024	10/10/2024	Yes	No