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Evidence-based prevention of dentine hypersensitivity: A randomized controlled trial to test three interventions

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 26/04/2016	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0644188383

Study information

Scientific Title
Evidence-based prevention of dentine hypersensitivity: A randomized controlled trial to test three interventions

Study objectives
1. Despite sensitive teeth being a common problem there is no evidence base for the treatments used with sensitivity returning soon after treatment. Furthermore, the amount of clinical time devoted to the management of hypersensitive teeth is significant. Therefore, an intervention, which is evidence based, simple and conservative, yet produces lasting relief would be desirable. This study investigates how effective
typical treatments are at providing immediate relief for the pain of sensitive teeth.
2. To determine if these treatments are effective over a period of six months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds East Ethics Committee (UK)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Oral Health: Dentine hypersensitivity

Interventions
The three test interventions will be:
1. No treatment
2. Application of a dentine bonding agent
3. Use of a desensitising toothpaste

In essence three groups of 25 subjects will be included in the study. As part of their routine examination patients will be screened for sensitive teeth. Having had chance to read the patient information leaflet they will be asked to sign a consent form if they are happy to be included in the study. They will then be randomly allocated to one of the three groups and they will receive one of the three interventions of interest. With the exception of the control these interventions are all approved medical devices that will only be used according to their directions for use. The patients response to the intervention will be tested at follow up examinations.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Immediate reduction of dental hypersensitivity

Secondary outcome measures
Prolonged reduction in dental hypersensitivity

Overall study start date
01/02/2009

Completion date
01/08/2009

Eligibility

Key inclusion criteria
75 patients with at least one tooth sensitive to hot, cold and sweet stimuli, which does not require any operative treatment (i.e. fillings) will be invited to participate in the study. As part of their routine examination patients will be screened for sensitive teeth according to our protocol. Having had chance to read the patient information leaflet they will then be asked to sign a consent form if they are happy to be included in the study.

Inclusion criteria:
1. At least one sensitive tooth. To be eligible subjects will be required to have at least one test tooth sensitive to an evaporative stimulus greater than 40 mm and less than 80 mm on the 100mm visual analogue scale (VAS).
2. Sensitive lesion not requiring restoration
3. Good oral hygiene and gingival health

Participant type(s)
Patient

Age group
Adult

Sex

Not Specified

Target number of participants
75, 25 per group

Key exclusion criteria
1. Under 18 years old
2. Sensitivity resulting from a lesion requiring any form of restoration
3. Sensitivity arising from heavily restored teeth
4. Poor oral hygiene or gingival health

Date of first enrolment
01/02/2009

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Dental Institute
Leeds
United Kingdom
LS2 9LU

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
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SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Greater Manchester Primary Care RM&G Partnership (ReGroup) (UK)

Funder Name
Oral Dental Health Research Trust

Funder Name
NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2013		Yes	No