

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

Submission date 28/09/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/04/2016	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

Immediate reduction of dental hypersensitivity

Key secondary outcome(s)

Prolonged reduction in dental hypersensitivity

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

England

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

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

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