ISRCTN30662154 https://doi.org/10.1186/ISRCTN30662154

Atraumatic restorative treatment for caries in the elderly - A study to assess a novel approach for the prevention of root caries

Submission date 17/05/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/05/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/01/2017	**Condition category** Oral Health	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of the study is to see how well tooth decay in elderly patients can be treated using a dental material (containing Chlorhexidine, which is commonly found in mouthwashes) when applied using a simple and painless method called Atraumatic Restorative Treatment. This is important because the elderly population are at a high risk of developing cavities (holes) in their teeth near the gum surface (called root caries).

Who can participate?
Adults aged 60 years or older, with at least one tooth with root caries that requires treatment.

What does the study involve?
Participants will be seen at a screening assessment to confirm that they are suitable to take part. Participants will then be invited for a treatment visit where photographs, plaque and saliva samples will be taken and the root caries treated with the dental material. Saliva and plaque samples will be collected at 1, 3 and 6 months and photographs taken at 6 months. Questionnaires will be completed at all visits.

What are the possible benefits and risks of participating?
Chlorhexidine is used safely in toothpastes and mouthwashes, so very few side effects are expected. The way the treatment is applied is likely to be simple and painless compared with conventional dental fillings. However additional visits are needed in order to collect plaque and saliva samples.

Where is the study run from?
Leeds Dental Institutes Dental Translational and Clinical Research Unit (DenTCRU), Leeds, UK

When is the study starting and how long is it expected to run for?
May 2013 - August 2014

Who is funding the study?
Dunhill Medical Trust

Who is the main contact?
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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
14230

Study information

Scientific Title
Atraumatic Restorative Treatment for CARies in the Elderly - A pilot non-randomised study to assess a novel approach for the prevention of root caries

Acronym
ARTCARE

Study objectives
The aim of this pilot study is to see how well tooth decay in elderly patients can be treated using a glass ionomer cement (GIC) dental material containing chlorhexidine (CHX) (which is commonly found in mouthwashes) when applied by dental therapists using the simple and painless method, Atraumatic Restorative Treatment (ART).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Leeds West, 22/02/2013, ref: 13/YH/0010

Study design
Non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Oral and Gastrointestinal; Subtopic: Oral and Gastrointestinal (all Subtopics); Disease: Oral & Dental

Interventions
GIC modified with chlorhexidine.

GIC with 5% chlorhexidine, applied once and left in place.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Reduction of bacteria in plaque samples; Timepoints: 6 months post treatment

Secondary outcome measures
1. Reduction of bacteria in plaque samples; Timepoints: 1 and 3 months post treatment
2. Reduction of bacteria in saliva samples; Timepoints: 1 and 3 month post treatment
3. Reduction of bacteria in saliva samples; Timepoints: 6 months post treatment
4. Survival rate of restorations; Timepoints: 6 months post treatment
5. Treatment delivery acceptability by dental therapists; Timepoints: Baseine, and at 1, 3 and 6 months post treatment

6. Treatment delivery acceptability by patients; Timepoints: Baseline and at 1, 3 and 6 months post treatment

Overall study start date
08/05/2013

Completion date
08/08/2014

Eligibility

Key inclusion criteria
1. Patients will be >=60 yrs (females and males)
2. Patients will have at least one lesion of root caries, which requires operative intervention.
3. Patients who are willingly to provide signed informed consent.
4. Patients who are willing to follow the research schedule for the period of the study.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
UK Sample Size: 34

Key exclusion criteria
1. Patients with no natural teeth.
2. Patients currently having antibiotic therapy or within 4 weeks of completion of a course of therapy with antibiotics.
3. Patients who are currently receiving or who have had radiotherapy of the head and neck region within the last 12 months.
4. Patients who are currently using or who have used toothpastes and/or mouthwashes containing chlorhexidine within the last 4 weeks.
5. Patients who have active periodontal disease which is likely to require treatment such as root surface debridement (RSD) during the study.
6. Patients who have any condition (including an allergy to chlorhexidine) which could be expected to interfere with the patients safety during the study.
7. Patients who demonstrate an inability to comply with study procedures.

Date of first enrolment
08/05/2013

Date of final enrolment
08/08/2014

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Faculty Research Office
University of Leeds
Room 10.110
Level 10 Worsley Building
Clarendon Way
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England
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LS2 9NL

Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name

Dunhill Medical Trust (UK) Grant Codes: R245/0212

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
HRA research summary			28/06/2023	No	No