

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

<b>Submission date</b> 17/05/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/05/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/01/2017	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Gillian Dukanovic  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Paul Brunton

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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  $\geq 60$  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

Leeds

England

United Kingdom

LS2 9NL

**Sponsor type**

University/education

**Website**

<http://www.leeds.ac.uk/>

**ROR**

<https://ror.org/024mrx33>

## **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?
<a href="#">HRA research summary</a>			28/06/2023	No	No