

# Anti-microbial varnish in the management of root caries in mentally and/or medically compromised older adults

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| <b>Submission date</b><br>23/01/2004   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>23/01/2004 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>26/08/2010       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

REC00054

# Study information

## Scientific Title

### Study objectives

Root caries is an increasing clinical problem affecting some 80 per cent of dentate elderly and especially those in residential homes and the house-bound. Root caries develops in older adults as the gingival tissues recede to expose the root surface and bacteria accumulate as the gingival margin. The measurement of root caries is difficult due to the high organic content of the root dentine, the proximity of the lesion to the gingival margin and the difficulty in gaining access to the disease in patients who may be frail and elderly or who give only limited co-operation with the treatment. The development of novel anti-microbial treatment regimens, in combination with conventional topical fluoride, may enable the development of new management protocols for the treatment of existing root carious lesions and for the prevention of new lesions.

We propose to determine, in a double-blind placebo controlled trial, the effects of a antimicrobial varnish containing chlorhexidine and thymol in conjunction with a remineralising, fluoride-containing varnish on clinical and microbiological parameters of root carious lesions. The control procedure will consist of the fluoride varnish and a placebo varnish in place of the chlorhexidine-thymol varnish. This project may demonstrate a new, non-restorative means of managing root carious lesions in institutionalised and home-bound individuals which would be more readily accepted by the patient and enable the practitioner to manage root caries more cheaply and more efficiently.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved by local medical ethics committee

### Study design

Double blind longitudinal randomised placebo controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

**Health condition(s) or problem(s) studied**

Root caries

**Interventions**

1. Use of antimicrobial varnish containing chlorhexidine and thymol in conjunction with a remineralising, fluoride-containing varnish on clinical and microbiological parameters of root carious lesions.
2. The control procedure will consist of the fluoride varnish and a placebo varnish in place of the chlorhexidine-thymol varnish.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Chlorhexidine and thymol in a remineralising, fluoride-containing varnish

**Primary outcome measure**

1. Effect on the salivary flora
2. Changes in clinical status
3. Dimensions of root lesions

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/1997

**Completion date**

01/04/1999

**Eligibility****Key inclusion criteria**

1. 150 elderly frail patients
2. Minimum of four teeth
3. At least one root caries lesion
4. Amenable to dental examination
5. Expected to survive the length of the study

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

150

**Key exclusion criteria**

Antibiotics less than four weeks ago.

**Date of first enrolment**

01/04/1997

**Date of final enrolment**

01/04/1999

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

King's College School of Medicine & Dentistry

London

United Kingdom

SE5 9RW

## **Sponsor information**

**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

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SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

# Funder(s)

## Funder type

Government

## Funder Name

NHS Executive London (UK)

# 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="#">Results article</a> | results | 01/09/2002   |            | Yes            | No              |