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

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/08/2010	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
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
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Sponsor type
Government

Website
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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?
Results article	results	01/09/2002		Yes	No