

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

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/08/2010	Condition category Oral Health	☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Double blind longitudinal randomised placebo controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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**

United Kingdom

England

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)

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

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	01/09/2002		Yes	No