Preventing oral cancer: a smoking cessation intervention in a dental setting for patients with potentially malignant lesions

Submission date	Recruitment status No longer recruiting	Prospectively registered		
07/12/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
29/12/2006	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
12/05/2011	Oral Health			

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

Study information

Scientific Title

Study objectives

To determine the feasibity of delivering two smoking cessation methodologies 5As (Ask, Advise, Assess, Assist, Arrange) and behavioural change counselling, to a cohort of patients who smoke and have been referred to an oral medicine department.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

- 1. The Glasgow Area Dental Ethics Committee on the 23/12/2003
- 2. The West Glasgow Ethics Committee 2 on the 20/09/2005 (protocol amendment)

Study design

Randomised, controlled, two armed trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Potentially malignant oral lesions

Interventions

Interventions group received advice based on the 5As (Ask, Advise, Assess, Assist, Arrange) and Nicotene Replacement Therapy (NRT) and behaviour change counselling.

Control group received treatment as usual.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Self reported quit rates
- 2. Validated by Carbon Monoxide (CO) and salivary cotinine

Secondary outcome measures

Self-reported changes in smoking behaviour, including reduction in cigarettes and increase in number and length of quit attempts.

Overall study start date

03/03/2004

Completion date

03/03/2004

Eligibility

Key inclusion criteria

Patients who smoke, and have been referred with suspicious oral lesion.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

120-150

Key exclusion criteria

Patients who have been diagnosed with oral cancer.

Date of first enrolment

03/03/2004

Date of final enrolment

03/03/2004

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre Level 8

Glasgow United Kingdom G2 3JZ

Sponsor information

Organisation

University of Glasgow (UK)

Sponsor details

University Avenue Glasgow Scotland United Kingdom G12 8QQ +44 (0)141 339 8855 p.ellis@gla.ac.uk

Sponsor type

University/education

Website

http://www.gla.ac.uk/

ROR

https://ror.org/00vtgdb53

Funder(s)

Funder type

Research organisation

Funder Name

Action on Smoking and Health (ASH) Scotland (UK) (ref: S1-32/S2-18) - website: www. ashscotland.org.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	02/05/2007		Yes	No