ISRCTN88337776 https://doi.org/10.1186/ISRCTN88337776

Salivary gland protection from iodine-131 therapy; evaluation of salivary stimulating tablets efficacy using 131 iodine dosimetry and salivary gland scintigraphy

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
09/09/2016

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
N0258113080

Study information

Scientific Title
Salivary gland protection from iodine-131 therapy; evaluation of salivary stimulating tablets efficacy using 131 iodine dosimetry and salivary gland scintigraphy

Study objectives
To compare iodine-131 salivary gland dosimetry in patients taking SST and those under a standard treatment protocol (sucking sweets).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Digestive System: Salivation

Interventions
Randomised test intervention versus standardised intervention, non-blinded (Phase 3).

Intervention Type
Other

Phase
Phase III

Primary outcome measure

If this study shows that SST has efficacy in salivary radioprotection then this could then be incorporated into standard radioiodine treatment protocols.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2002

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2002

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuclear Medicine
Sutton, Surrey

United Kingdom
SM2 5PT

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
The Royal Marsden NHS Trust (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