ISRCTN67519330 https://doi.org/10.1186/ISRCTN67519330

Randomised double-blind placebo controlled study to determine whether the use of selective digestive decontamination pastilles reduces radiation mucositis

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 02/02/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HN9

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind placebo controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Head and neck

Interventions
1. Group A: Active SSD pastille (Polymyxin E 2 mg, Tobramycin 1.8 mg and Amphotericin B 10 mg). Treatment to start on the day radiotherapy begins, one pastille four times daily until radiation reactions have settled.
2. Group B: Placebo pastille four times daily. Treatment to start on the first day of radiotherapy until radiation reactions have settled.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1999

Completion date
31/12/2000

Eligibility

Key inclusion criteria
1. Patients with head and neck cancer receiving potentially curative doses of radiotherapy
2. Eligible patients may have squamous carcinoma, adenocarcinoma or salivary tumours arising in the oral cavity, nas -oro, or hypopharynx, larynx and paranasal sinuses
3. Stages T1-T4
4. No allergy to Polymyxin E, Tobramycin or Amphotericin B
5. No pre-existing oral or oropharyngeal infection

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1999

Date of final enrolment
31/12/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
UK Co-ordinating Committee for Cancer Research (UKCCCR)

Sponsor details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Sponsor type
Government

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Not defined

Funder Name
Not available

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	01/07/1996		Yes	No