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

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

### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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