

# A comparison of bethanechol chloride and artificial saliva in the management of xerostomia in patients with cancer

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| <b>Submission date</b><br>30/09/2004   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>30/09/2004 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>16/12/2014       | <b>Condition category</b><br>Digestive System     | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr A N T Davies

### Contact details

Level 1, The Old Building  
Bristol Royal Infirmary  
Malborough Street  
Bristol  
United Kingdom  
BS2 8HW

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0264120257

# Study information

## Scientific Title

A comparison of bethanechol chloride and artificial saliva in the management of xerostomia in patients with cancer

## Study objectives

To compare the efficacy of bethanechol chloride and Saliva Orthana in the management of xerostomia in patients with advanced cancer

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Digestive System: Xerostomia

## Interventions

Participants will be randomised to one week's treatment with:

1. Bethanechol chloride or
2. Saliva Orthana

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Bethanechol chloride, Saliva Orthana

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/10/2002

**Completion date**

30/04/2005

## Eligibility

**Key inclusion criteria**

54 patients >18 years advanced cancer, xerostomia Eastern Cooperative Oncology Group (ECOG) status 0-3

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

54

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/10/2002

**Date of final enrolment**

30/04/2005

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Bristol Royal Infirmary**  
Bristol  
United Kingdom  
BS2 8HW

## **Sponsor information**

**Organisation**  
Department of Health

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

**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
United Bristol Healthcare 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