

# 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

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### Contact details

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Bristol Royal Infirmary**

Bristol

United Kingdom

BS2 8HW

**Sponsor information****Organisation**

Department of Health

# **Funder(s)**

## **Funder type**

Hospital/treatment centre

## **Funder Name**

United Bristol Healthcare NHS Trust (UK)

# **Results and Publications**

## **Individual participant data (IPD) sharing plan**

## **IPD sharing plan summary**

Not provided at time of registration