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

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/12/2014	**Condition category** Digestive System	[_] 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
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