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AS Orthana® versus Biotène Oralbalance® for patients with dry mouth

Submission date	Recruitment status	[_] Prospectively registered
09/10/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/10/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/04/2016	Digestive System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dry mouth is a common problem with a range of causes. It may be due to a reduction in the quantity of saliva produced, or a change in the composition of saliva. A feeling of dry mouth may also be present in people with normal saliva production. Radiotherapy or chemotherapy for head and neck cancers, and diseases such as Sjögrens Syndrome, may result in reduced saliva production.
Many commonly prescribed medications are associated with a feeling of dry mouth, despite normal saliva production. As well as difficulty in speaking, chewing and swallowing, prolonged dry mouth may result in increased risk of tooth decay and reduced quality of life. In many sufferers, dry mouth cannot be cured, but effective ways for people to manage dry mouth symptoms are available. Simple measures such as drinking frequent sips of water, sucking ice cubes and chewing sugar-free gum will often help, and may be all that is needed in many cases. Artificial saliva or medication to stimulate the salivary glands is sometimes used. Your doctor may prescribe a spray, gel or lozenge which acts as a substitute for saliva. Each dose only lasts a short time and so they need to be used frequently. Some people find some artificial saliva products more helpful than others. In practice, doctors are prescribing a range of products that substitute saliva and that may help relieve the sensation of dry mouth, altered taste sensation or even speech difficulty. Unfortunately, at present there is no good evidence on which product(s) are most effective in relieving dry mouth. In this study, we would like to compare two topical products which are already used for treatment of dry mouth to see if there is one that patients prefer to use. In this study we would ask patients to compare both products and provide feedback to us about their opinion of the effectiveness of each. We hope this will add to our knowledge, so that we can tailor our management of dry mouth.

Who can participate?
Anyone who ha been identified by doctor or nurse as someone who is currently experiencing dry mouth.

What does the study involve?
We will ask you to complete a short questionnaire and rate your symptoms on scale at the start of the study. We will then provide you with bag containing two artificial saliva products to be used. The products will be labelled (A) and (B). You will start by using product (A) for five days.

At the end of this time, we will ask you to complete a questionnaire and rate your symptoms on scale. You will then start using product (B) for another five days, and then we will ask you to complete a third questionnaire and rate your symptoms on scale. During the study, you will be asked to only use the toothpaste that is supplied in the study pack, as your usual toothpaste may lessen the effect of the artificial saliva products.

What are the possible benefits and risks of participating?
You may find your mouth dryness improves. Having your dry mouth assessed at the start of the study may help. In addition, the study salivary product may help. Completing the questionnaire may be helpful to understand more about your symptoms. If you have any problems at any time, you can discuss these with your study doctor. We cannot promise the study products will help you, but the information we get from this study may help us to make the best possible decision about treatment of people with similar conditions in the future. The products being used are both considered part of standard care and there is no risk identified from using these artificial salivary products, other than you may not find them effective.

Where is the study run from?
North Manchester General Hospital, which is part of the Pennine Acute Hospitals NHS Trust.

When is study starting and how long is it expected to run for?
The study will start recruitment from 12/10/2012 to 30/01/2013.

Who is funding the study?
The study is funded from research grant from the Department of Palliative Medicine at North Manchester General Hospital, which is part of the Pennine Acute Hospitals NHS Trust.

Who is the main contact?
Dr Ehab Ibrahim
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
(Version 1.7)

Study information

Scientific Title
Comparative study to evaluate effectiveness of mucin saliva product AS Orthana® versus Biotène Oralbalance® Gel for patients with dry mouth

Study objectives
Studies have investigated the range of artificial saliva substitutes and have suggested that topical artificial saliva substitutes are reported by many people to be beneficial in the management of dry mouth. There is a paucity of direct comparative studies of saliva substitutes. In addition, these studies do not provide a clear hierarchy of use or patient preference. They indicate that patients may prefer one preparation above another and that, if one topical artificial saliva substitute does not provide adequate benefit in people with dry mouth, it may be worth trying a different preparation. Patient preference is likely to influence product acceptability and compliance.There are many artificial saliva products available in United Kingdom.This study will compare patient feedback of two artificial saliva products which should help us to understand:

1. Which product is more effective in regard to sense of oral dryness, chewing difficulty, swallowing difficulty, speech difficulty, burning sensations and ease of use (regardless of the cause of dry mouth sensation)?
2. Which product is more effective in regard to improvement in The Summated Xerostomia Inventory?
3. Which product is preferred by patients?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Research Ethics Committee (North West -Cheshire), 27/09/2012, ref: 12/NW/0657

Study design
Single blinded crossover randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Dry mouth / xerostomia

Interventions
Participants will be patients under the care of the Oral Maxillofacial Surgery Department who have dry mouth. Information about the study will be given to patients who meet the inclusion criteria, then the Principal Investigator (or Co-Investigator) will explain the study and answer any questions before obtaining informed consent for participation where appropriate. Baseline Visual Analogue Scales (VAS) and The Summated Xerostomia Inventory Questionnaire will be completed by participants before starting the clinical intervention. The subjective assessment of both treatments will be evaluated by means of VAS and The Summated Xerostomia Inventory Questionnaire.

In this crossover study, each participant will receive 5 days of treatment with one of the artificial saliva products, 'washout' overnight, then 5 days of treatment with the other artificial saliva product. Each participant will use both products over the ten-day study period. In this way, the number of participants required for the study is less than in a parallel study, as participants act as their own controls.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
AS Orthana®, Biotène Oralbalance®

Primary outcome measure
1. Improvement of patient symptoms reflected by VAS
2. The Summated Xerostomia Inventory Questionnaire

At baseline, after 5 days from start of the first product and after 5 days from the start of second product.

Secondary outcome measures
Patient preference for one of the two products measured after 5 days from the start of second product

Overall study start date
12/10/2012

Completion date
30/01/2013

Eligibility

Key inclusion criteria
1. Patients who are referred to the Oral Maxillofacial Surgery Department at North Manchester General Hospital with dry mouth / xerostomia
2. Patients whom clinicians have advised to use an artificial saliva product
3. Patients aged 18 years and over from of either gender
4. Patients must be able to communicate in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20-30

Key exclusion criteria
1. Patients who lack the capacity to consent to participation in the study
2. Patients below 18 years old
3. Patients who are unable communicate in English
4. Patients who are felt to be in the last hours or days of life (i.e. on the Liverpool Pathway for Care of the Dying Patient - LCP)
5. Patients involved in another current research

Date of first enrolment
12/10/2012

Date of final enrolment
30/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Palliative Medicine
Manchester
United Kingdom
M8 5RB

Sponsor information

Organisation
Pennine Acute Hospitals NHS Trust (UK)

Sponsor details
Research and Development Department
Delaunays Road
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05ga8m074

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Palliative Medicine at North Manchester General Hospital (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