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Treatment Alternatives for acute Sore Throat in Everyday practice

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/02/2018	Signs and Symptoms	

Plain English summary of protocol

Background and study aims

Upper respiratory tract illness (URTI) is the most common respiratory illness experienced by the general population and sore throat is the most common URTI managed in the NHS, costing the NHS an estimated £25 million in consultations alone. Antibiotic use for respiratory tract illnesses has decreased since 1997 but is still double the rate of other Northern European countries, and costs the NHS an additional £6-12 million in prescribing costs per annum. Xylitol (used in some sugar-free gum) is a birch sugar, and causes local 'bacterial interference' by inhibiting the growth and adherence of bacteria to the throat. Sorbitol has no such effect and will be used as a 'placebo' (dummy) gum. Probiotics, which are also available commercially, are benign non-pathogenic bacteria and may also act through local 'bacterial interference' by a different mechanism and may also have an effect on non-specific general activation of the immune system. Although there are studies that support the use of both xylitol and probiotics in the management of recurrent infections, this evidence needs confirming, and we particularly need evidence about their effectiveness for either symptoms or recurrence of sore throat. In addition there is no clear evidence concerning the effect of chewing any kind of gum on the symptoms of sore throat. The effectiveness of chewing xylitol and probiotics in URTIs requires urgent clarification both for the general public and for the health service. Since probiotics and xylitol act via different mechanisms, a study is needed to assess the possible interaction of both interventions together. This study aims to investigate the effect of xylitol and probiotics on symptoms and recurrence of sore throat.

Who can participate?

Patients over the age of 16, presenting with acute sore throat

What does the study involve?

Participants are provided with instructions and randomly allocated to receive a treatment pack containing 3 months' supply of either just probiotic capsules (to take one capsule daily) or probiotic capsules and chewing gum (to chew five pieces a day). As some people get better just because they are taking something they believe to be helpful (a placebo), some of the packs have pretend treatments in them - they look and taste the same as the real thing and participants won't know which one they've got until the end of the study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study was lead and run by the trial management team in Southampton, and participants were recruited from 83 practices from Land's End to Ipswich (UK)

When is the study starting and how long is it expected to run for?
November 2008 to January 2015

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Ms Tammy Thomas

Contact information

Type(s)
Scientific

Contact name
Ms Tammy Thomas

Contact details
Aldermoor Health Centre
Aldermoor Close
Southampton
United Kingdom
SO16 5ST

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5676

Study information

Scientific Title
A primary care randomised controlled trial of probiotics, xylitol and sorbitol for acute sore throat

Acronym
TASTE

Study objectives
This study aims to investigate the effect of xylitol and probiotics on symptoms and recurrence of sore throat.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire REC, 28/02/2005, ref: 05/Q1702/11

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Patients will be approached by either advertising in the practice, when seeing their doctor/nurse (who will provide information to the patient with the consent form) or by writing to patients with known recurrent sore throat identified from a database search. Patients who agree to take part will be allocated treatment packs in numerical order provided by the investigators with the surgery recording ID numbers.

Probiotics, sorbitol and xylitol for acute sore throat. Patients randomised to probiotics/placebo will be required to take one capsule per day for 3 months. Patients randomised to chew active /placebo gum will be asked to chew five pieces per day (for 5 minutes) for 3 months. All treatment groups will be followed up for a further 3 months.

Follow-up length: 6 months
Study entry: single randomisation only

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
The mean score for sore throat and difficulty swallowing during 2 - 5 days after presentation

Secondary outcome measures
1. Time to resolution of sore throat
2. Time taken off work or unable to do normal activities
3. Satisfaction with treatment

Overall study start date
01/11/2008

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Presenting with acute sore throat
2. Over the age of 16 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 401; UK Sample Size: 401

Key exclusion criteria
1. History suggestive of quinsy
2. Previous rheumatic fever, glomerulonephritis
3. Phenylketonuria
4. Allergy to xylitol, sorbitol or probiotics
5. Patients unwilling or unable to self medicate with gum or probiotics for the duration of the study or complete outcome measures
6. Subjects with serious chronic disorders where antibiotics are automatically needed (e.g. cystic fibrosis)
7. Suspected pregnancy
8. Immune deficiency

Date of first enrolment
01/11/2008

Date of final enrolment

31/07/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Aldermoor Health Centre
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
University Road
Southampton
England
United Kingdom
SO17 1BJ

Sponsor type
University/education

Website
http://www.soton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name

Programme Grants for Applied Research (ref: RP-PG-0407-10098)

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	18/12/2017		Yes	No