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A clinical study to assess the effectiveness of Strepsils sore throat lozenges

Submission date	Recruitment status	[_] Prospectively registered
12/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/08/2013	Respiratory	

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
TH0817

Study information

Scientific Title
A multicentre, randomised, double blind, placebo-controlled, parallel group, single dose study of the efficacy of two flavour variants of Strepsils throat lozenges in the relief of sore throat due to upper respiratory tract infection

Study objectives
Do Strepsils lozenges improve sore throat symptoms over 2 hours?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fife, Forth Valley and Tayside Research Ethics Service approved on the 15th December 2008 (ref: FB/08/S0501/91)

Study design
Randomised single dose placebo controlled parallel group design

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Sore throat

Interventions
1. Strepsils lozenge (0.6 mg 2,4-dichlorobenzylalcohol, 1.2 mg amylmetacresol) single dose, oral
2. Placebo lozenge, single dose, oral

This trial is of a single dose with a 2 hour follow up only.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Strepsils throat lozenges

Primary outcome measure
Area under the change from baseline curve (AUC) in severity of throat soreness, from 0 to 2 hours (using 11 point categorical throat soreness scale)

Secondary outcome measures
1. Change from baseline in severity of throat soreness (using the 11 point throat soreness scale) at 1,5, 10, 15, 30, 45, 60, 75, 90, 105 and 120 minutes post-dose
2. Onset of analgesia defined as time to first reporting 'moderate pain relief' (which is the midpoint on the 7 point sore throat relief scale)
3. Total sum of pain relief ratings: defined as the AUC from baseline to 2 hours post first dosing for sore throat relief
4. Sore throat relief at 1, 5, 10, 15, 30, 45, 60, 75, 90, 105 and 120 minutes post-dose
5. AUC from baseline to 2 hours for the change from baseline in difficulty swallowing
6. Change from baseline in difficulty in swallowing at 1, 5, 10, 15, 30, 45, 60, 75, 90, 105 and 120 minutes post-dose
7. AUC for throat numbness measurements from 1 to 120 minutes
8. Throat numbness at 1, 5, 10, 15, 30, 45, 60, 75, 90, 105 and 120 minutes post-dose
9. Overall treatment rating at 2 hours
10. Responses to the questions from the consumer questionnaire

Overall study start date
12/01/2009

Completion date
20/02/2009

Eligibility

Key inclusion criteria
1. Aged greater than or equal to 16 to less than or equal to 75 years
2. Male and female patients
3. Primary diagnosis: patients with sore throat of onset within the past 4 days (i.e. less than or equal to 4 days) due to upper respiratory tract infection (URTI)
4. Patients who had a sore throat (greater than or equal to 6) on the Throat Soreness Scale at baseline
5. Objective findings that confirm the presence of tonsillopharyngitis (greater than or equal to 3 points on the expanded 21-point Tonsillopharyngitis Assessment)
6. Patients who gave written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
225

Key exclusion criteria
1. Any previous history of allergy or known intolerance to the study drug or the following formulation constituents: amylmetacresol (AMC), 2,4-dichlorobenzyl alcohol (DCBA), anise oil, peppermint oil, natural menthol, menthol synthetic, xylitol, mint, eucalyptus oil, liquid sucrose, liquid glucose, tartaric acid gran 571 GDE, ponceau 4R, edicol E124, carmoisine edicol E122, sugar, cream, anthocyanin, ginger, wasabi, blackcurrant and plum
2. Those whose sore throat had been present for more than 4 days
3. Those who had evidence of mouth breathing
4. Those who had evidence of severe coughing
5. Those who had any disease that could compromise breathing, e.g., bronchopneumonia
6. Those who had taken any medicated confectionary, throat pastille, spray, or any product with demulcent properties such as boiled sweets in the previous two hours
7. Those who had used any sore throat medication containing a local anaesthetic within the past 4 hours
8. Those who had used any analgesic, antipyretic or cold medication (e.g., decongestant, antihistamine, antitussive or throat lozenge) within the previous 8 hours
9. Those who have used a longer acting or slow release analgesic during the previous 24 hours, e. g., piroxicam and naproxen
10. Those taking antibiotics during the previous 14 days
11. Those with any painful condition that may have distracted attention from sore throat pain, e. g., mouth ulcers, etc.
12. Those with a history of severe renal impairment
13. Those with a history of severe hepatic impairment
14. Those with a history of alcohol abuse or who stated that they regularly consume alcohol in excess of the recommended amounts (excessive alcohol greater than 21 units per week for females and greater than 28 units per week for males)
15. Those unable to refrain from smoking during their stay in the investigative site
16. Women of childbearing potential, who reported they were pregnant or lactating, seeking pregnancy or failing to take adequate contraceptive precautions (i.e., an oral or injectable contraceptive, an approved hormonal implant or topical patch or an intrauterine device). Adequate contraception should also include abstinence, barrier contraception and partner vasectomy. A women of childbearing potential was defined as any female who is less than 2 years post-menopausal or has not undergone an hysterectomy or surgical sterilisation, e.g. bilateral tubal ligation, bilateral ovariectomy (oophorectomy).
17. Those previously randomised into the study
18. Those who have participated in a clinical trial in the previous 30 days. Thirty days were calculated from time of last dosing in the prior trial to time of anticipated dosing in this trial.
19. Those unable in the opinion of the investigator to comply fully with the study requirements, e.g., such as those who could not comprehend or correctly use the pain rating scales

Date of first enrolment
12/01/2009

Date of final enrolment
20/02/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
CPS Research
Glasgow
United Kingdom
G20 0XA

Sponsor information

Organisation
Reckitt Benckiser Healthcare (UK)

Sponsor details
Dansom Lane
Hull
United Kingdom
HU8 7DS

Sponsor type
Industry

Website
http://www.rb.com/home

ROR
https://ror.org/01g87hr29

Funder(s)

Funder type
Industry

Funder Name
Reckitt Benckiser Healthcare (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/02/2011		Yes	No
HRA research summary			28/06/2023	No	No