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Investigating the acceptability of a single dose of Strepsils Strawberry sugar free and Orange colour free with Vitamin C lozenges in children

Submission date
30/08/2012

Recruitment status
No longer recruiting

Registration date
05/09/2012

Overall study status
Completed

Last Edited
29/08/2013

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In 2006, the European Agency for the Evaluation of Medicinal Products (EMEA) stated that the main consideration when developing medications for children should be its acceptability to the child. It described the difficulty experienced by children in recognising tastes and suggested that their ability to recognise flavour may also be affected by the concentration of the flavour and the appearance of the medication. The purpose of this taste testing study is to investigate the acceptability of the flavours of Strepsils strawberry sugar free and orange colour free with vitamin C in children aged six to twelve years old.

Who can participate?
Healthy, male and female children aged between 6 and 12 years.

What does the study involve?
Participants will receive a single Strepsils strawberry sugar free lozenge followed at least 15 minutes later by a single Strepsils orange colour free with vitamin C lozenge. All participants will taste the strawberry flavoured lozenge first, followed by the orange flavoured lozenge. Each participant will suck the lozenge for 1 minute and will be instructed not to chew, crunch or swallow the lozenge and to spit it out after 1 minute. After this they will be asked a series of questions on a questionnaire.

What are the possible benefits and risks of participating?
There is no anticipated benefit for the participants. The safety of Strepsils lozenges has been well established over many years of use as an over the counter product and the potential risks to subjects are considered to be low.

Where is the study run from?
Aspect Clinical, Ledbury.

When is the study starting and how long is it expected to run for?
The study ran from November to December 2010.

Who is funding the study?
Reckitt Benckiser, UK.

Who is the main contact?
Emma Field
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Contact information

Type(s)
Scientific

Contact name
Dr Alex Thompson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TH1016

Study information

Scientific Title
An open label taste testing study in healthy children to investigate the acceptability of a single dose of Strepsils Strawberry sugar free and Orange colour free with Vitamin C lozenges

Study objectives
To assess the taste acceptability in children, aged between 6 and 12 years, of two flavour vairants of an AMC 0.5mg and DCBA 1.2mg sore throat lozenge (strawberry and orange)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Reading Independent Ethics Committee

Study design
Open label single dose taste test

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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
Healthy subjects

Interventions
AMC 0.5mg and DCBA 1.2mg sore throat lozenge

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The percentage of children that rated each lozenge above four on the hedonic facial scale.

Secondary outcome measures
Descriptive summary statistics (mean, standard deviation, median, min, max) and the frequencies (with percentages) of the hedonic facial scale scores for each lozenge were presented.

Overall study start date
17/11/2010

Completion date
10/12/2010

Eligibility

Key inclusion criteria

1. Aged 6 to 12 years inclusive
2. Male or female
3. Healthy volunteers

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
102

Key exclusion criteria
1. A history of hereditary fructose intolerance
2. A history of sensitivity to an analgesic medication, its ingredients or related products, or any previous history of allergy or known intolerance to dichlorobenzyl alcohol, amylmetacresol, any colouring, flavouring, preservative, sweetener or surfactant. (A list of all constituents that could possibly have given rise to allergy is given in Appendix III of the protocol)
3. A history of hepatic or renal impairment, cardiac disease or high blood pressure
4. A history of asthma
5. A history of peptic or duodenal ulcers, gastro-intestinal bleeding or frequent dyspepsia, e.g. heartburn or indigestion
6. A respiratory infection or any other condition that could have affected subjects perception of taste
7. More than two siblings already participating in the trial
8. Previous completion of the study
9. Participation in a taste testing study within three days of the screening visit
10. Participation in a clinical trial involving consumption of an investigational medicinal product within one month of the screening visit
11. Inability in the opinion of the Medical Investigator to comply fully with the study requirements
12. Use of prescription medications within seven days of the taste testing day
13. Use of analgesic or anaesthetic medication on the day of taste testing
14. Consumption of food or drink that was likely to have affected the subjects ability to taste the product (e.g. highly spiced meals, mint or menthol based products) on the day of taste testing
15. Use of non-prescription medication in the four hours before taste testing
16. Current mouth ulcer
17. Any dental work on the day of taste testing

Date of first enrolment
17/11/2010

Date of final enrolment
10/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hill House
Ledbury
United Kingdom
HR8 2AA

Sponsor information

Organisation
Reckitt Benckiser Healthcare (UK)

Sponsor details
Dansom Lane
Hull
United Kingdom
HU8 7DS

Sponsor type
Industry

Website
http://www.rb.com/

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	01/06/2013		Yes	No