

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	☐ Prospectively registered ☐ Protocol
Registration date 05/09/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/08/2013	Condition category Other	☐ Individual participant data

Plain English summary of protocol

Background and study aims

In 2006, the European Agency for the Evaluation of Medicinal Products (EMA) 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
Emma.Field@ReckittBenckiser.com

Contact information

Type(s)
Scientific

Contact name
Dr Alex Thompson

Contact details
Hill House
4A Bye Street
Ledbury
United Kingdom
HR8 2AA

Additional identifiers

Protocol serial number
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 variants 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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

12 years

Sex

All

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

United Kingdom

England

Study participating centre

Hill House

Ledbury

United Kingdom

HR8 2AA

Sponsor information

Organisation

Reckitt Benckiser Healthcare (UK)

ROR

<https://ror.org/01g87hr29>

Funder(s)

Funder type

Industry

Funder Name

Reckitt Benckiser Healthcare (UK)

Results and Publications

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