An open-label, single-dose, randomized, two-period, two-treatment, two-sequence, crossover, oral dissolution study to assess sugar free and sugared cetylpyridinium chloride (CPC-1.4mg) and benzocaine (10mg) lozenges in healthy subjects

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The primary objective of this study is to confirm that the dissolution profiles of a sugar-free and sugared lozenge containing CPC/benzocaine (1.4mg/10 mg) are comparable following a single dose in healthy adult subjects.The secondary objectives of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51112

Source
ToetsingOnline

Brief title
CS0353-200147

Condition

- Other condition

Synonym
sore throat

Health condition

temporary supportive treatment in painful inflammations of the mucosa of the mouth and throat (sore throat).

Research involving
Human

Sponsors and support

Primary sponsor: Reckitt Benckiser Healthcare (UK) Limited (RB)
Source(s) of monetary or material Support: Reckitt Benckiser Healthcare (UK) Limited (RB)

Intervention

Keyword: compare, lozenges, open-label, oral dissolution

Outcome measures

Primary outcome

To confirm that the dissolution profiles of a sugarfree and sugared lozenge

containing CPC/benzocaine (1.4 mg/10 mg) are comparable following single dose

in healthy adult subjects.

Secondary outcome

To determine the safety and local tolerability of the CPC/benzocaine (1.4 mg/10

mg) sugar-free and sugared lozenge.

To determine the oral dissolution duration of the CPC/benzocaine (1.4 mg/10 mg)

sugar-free and sugared lozenge.

Study description

Background summary

RB has developed a sugar-free lozenge containing the same active pharmaceutical ingredients (API) as the sugared lozenge but with new

excipients, with an aim of replacing the sugared formula on the market to expand the patient group to those patients who cannot, or do not wish to take a lozenge containing sugar. It is important to understand whether the change in excipients affects the local availability of the APIs (CPC and benzocaine). This clinical study has been designed to evaluate the similarity of the dissolution profiles by comparing the weight loss of the CPC/benzocaine sugar-free and sugared lozenges over time.

Study objective

The primary objective of this study is to confirm that the dissolution profiles of a sugar-free and sugared lozenge containing CPC/benzocaine (1.4 mg/10 mg) are comparable following a single dose in healthy adult subjects.
The secondary objectives of this study, are as follows:
* To determine the safety and local tolerability of the CPC/benzocaine (1.4 mg/10 mg) sugar-free and sugared lozenge.
* To determine the oral dissolution duration of the CPC/benzocaine (1.4mg/10 mg) sugar-free and sugared lozenge.

Study design

This is an open label, single-dose, randomised, two-period, two-treatment, twosequence, crossover, local availability study.
Subjects will attend the Clinical Unit on two occasions; Screening Visit and Dosing Period Visit (which consists of two dosing days * Dosing Day 1 and Dosing Day 2), after which subjects will receive a follow-up telephone call after the dosing period.

Intervention

The following IP will be used for this study:
* Test Product: CPC/benzocaine 1.4 mg/10 mg sugar-free lozenge. A round, colourless biconvex lozenge with an S-shaped symbol on both sides.
* Reference Product: CPC/benzocaine 1.4 mg/10 mg sugared lozenge. A round, green biconvex lozenge with an S-shaped symbol on both sides (Marketing Authorisation Number 4974.00.00).

Study burden and risks

Since the study is being executed in healthy volunteers, there are no anticipated benefits of the IMP. Please see the IB for further information.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subject has provided written informed consent.
Subject is male or female and aged: 18 years to 55 years.
Subject has a Body Mass Index (BMI) of * 18.5 and * 30.0 kg / m2
Subject is healthy and free of clinically significant abnormal findings as determined by medical history, physical examination and vital signs.

Exclusion criteria

Female subject who is pregnant as confirmed by a positive pregnancy test or is lactating.
Subject has a current and previous clinically significant medical history as

deemed by the Investigator including but not limited to cardiovascular, salivary gland disorders (e.g. xerostomia, Sjogren*s syndrome, drooling of saliva, stones or infections), respiratory, gastro-intestinal (nausea or vomiting), neurological, metabolic and psychiatric disorders.
Subject has oral mucosal damage (erythema/ulceration/induration) or presence of clinically significant sore throat, gingivitis, or oral thrush.
Subjects with any oromucosal conditions or salivary gland conditions that affect saliva production.
Subject has toothache, is intended to have dental surgery or teeth treatment within 14 days prior to the first drug administration to end of study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2021
Enrollment:	16
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	CPC/benzocaine (1.4 mg/10 mg) sugar-free lozenge
Generic name:	CPC (1-hexadecylpyridinium chloride monohydrate)/benzocaine
Product type:	Medicine
Brand name:	Dolo-Dobendan®
Generic name:	Nap.

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	31-12-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-04-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-05-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-05-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-004729-22-NL
CCMO	NL76074.056.20

Study results

Results posted: 14-02-2022

First publication
03-11-2021