Clinical trial results:
Phase II study to assess bacterial count reduction of three Octenidine mouthwash concentrations in comparison to a placebo in patients with mild gingivitis

Summary

EudraCT number	2013-002708-14
Trial protocol	DE
Global end of trial date	17 February 2014

Results information

Result version number	v1 (current)
This version publication date	09 September 2021
First version publication date	09 September 2021

Trial information

Trial identification

Sponsor protocol code	OML0113

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Schülke & Mayr GmbH
Sponsor organisation address	Robert-Koch-Straße 2, Norderstedt, Germany, 22851
Public contact	Clinical trials information, Schülke & Mayr GmbH, 49 40521000, info@schuelke.com
Scientific contact	Clinical trials information, Schülke & Mayr GmbH, 49 40521000, info@schuelke.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 February 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 February 2014
Global end of trial reached?	Yes
Global end of trial date	17 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To identify the most efficacious octenidine dihydrochloride concentration regarding bacterial count reduction in comparison to placebo

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 October 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 90
Worldwide total number of subjects	90
EEA total number of subjects	90

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	88
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at 2 clinical sites in Germany. The first patient was recruited on 28 Oct 2013 and the last patient on 7 Jan 2014.

Pre-assignment

Screening details:

105 patients were screened; 15 of which were not randomised because they did not meet the eligibility criteria.

Period 1

Period 1 title	Period 1
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Data analyst, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	OML 0.1% then placebo

Arm description:

Treatment with OML 0.1% in Period 1, followed by placebo in Period 2

Arm type	Experimental
Investigational medicinal product name	Octenidine dihydrochloride 0.1%
Investigational medicinal product code	OML
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	Placebo then OML 0.1%

Arm description:

Treatment with placebo in Period 1, followed by OML 0.1% in Period 2

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	OML 0.15% then placebo

Arm description:

Treatment with OML 0.15% in Period 1, followed by placebo in Period 2

Arm type	Experimental

Investigational medicinal product name	Octenidine dihydrochloride 0.15%
Investigational medicinal product code	OML
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	Placebo then OML 0.15%

Arm description:

Treatment with placebo in Period 1, followed by OML 0.15% in Period 2

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	OML 0.2% then placebo

Arm description:

Treatment with OML 0.2% in Period 1, followed by placebo in Period 2

Arm type	Experimental
Investigational medicinal product name	Octenidine dihydrochloride 0.2%
Investigational medicinal product code	OML
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	Placebo then OML 0.2%

Arm description:

Treatment with placebo in Period 1, followed by OML 0.2% in Period 2

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Number of subjects in period 1	OML 0.1% then placebo	Placebo then OML 0.1%	OML 0.15% then placebo
Started	14	15	15
Completed	14	15	15

Number of subjects in period 1	Placebo then OML 0.15%	OML 0.2% then placebo	Placebo then OML 0.2%
Started	15	16	15
Completed	15	16	15

Period 2

Period 2 title	Period 2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	OML 0.1% then placebo

Arm description:

Treatment with OML 0.1% in Period 1, followed by placebo in Period 2

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	Placebo then OML 0.1%

Arm description:

Treatment with placebo in Period 1, followed by OML 0.1% in Period 2

Arm type	Experimental
Investigational medicinal product name	Octenidine dihydrochloride 0.1%
Investigational medicinal product code	OML
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	OML 0.15% then placebo

Arm description:

Treatment with OML 0.15% in Period 1, followed by placebo in Period 2

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	Placebo then OML 0.15%

Arm description:

Treatment with placebo in Period 1, followed by OML 0.15% in Period 2

Arm type	Experimental
Investigational medicinal product name	Octenidine dihydrochloride 0.15%
Investigational medicinal product code	OML
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	OML 0.2% than placebo

Arm description:

Treatment with OML 0.5% in Period 1, followed by placebo in Period 2

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Arm title	Placebo then OML 0.2%

Arm description:

Treatment with placebo in Period 1, followed by OML 0.2% in Period 2

Arm type	Experimental
Investigational medicinal product name	Octenidine dihydrochloride 0.2%
Investigational medicinal product code	OML
Other name	
Pharmaceutical forms	Oromucosal solution
Routes of administration	Oromucosal use

Dosage and administration details:

Use of study drug twice daily (rinsing the oral cavity with 10 mL study drug for 30 s) over a period of 4.5 days.

Number of subjects in period 2	OML 0.1% then placebo	Placebo then OML 0.1%	OML 0.15% then placebo
Started	14	15	15
Completed	14	15	15

Number of subjects in period 2	Placebo then OML 0.15%	OML 0.2% than placebo	Placebo then OML 0.2%
Started	15	16	15
Completed	15	16	15

Baseline characteristics

Reporting groups	
Reporting group title	Period 1

Reporting group description: -

Reporting group values	Period 1	Total	
Number of subjects	90	90	
Age categorical Units: Subjects			
Adults (18-64 years)	88	88	
From 65-84 years	2	2	
Age continuous Units: years			
arithmetic mean	28.4		
standard deviation	± 10.9	-	
Gender categorical Units: Subjects			
Female	58	58	
Male	32	32	

End points

End points reporting groups

Reporting group title	OML 0.1% then placebo
Reporting group description:	
Treatment with OML 0.1% in Period 1, followed by placebo in Period 2	
Reporting group title	Placebo then OML 0.1%
Reporting group description:	
Treatment with placebo in Period 1, followed by OML 0.1% in Period 2	
Reporting group title	OML 0.15% then placebo
Reporting group description:	
Treatment with OML 0.15% in Period 1, followed by placebo in Period 2	
Reporting group title	Placebo then OML 0.15%
Reporting group description:	
Treatment with placebo in Period 1, followed by OML 0.15% in Period 2	
Reporting group title	OML 0.2% then placebo
Reporting group description:	
Treatment with OML 0.2% in Period 1, followed by placebo in Period 2	
Reporting group title	Placebo then OML 0.2%
Reporting group description:	
Treatment with placebo in Period 1, followed by OML 0.2% in Period 2	
Reporting group title	OML 0.1% then placebo
Reporting group description:	
Treatment with OML 0.1% in Period 1, followed by placebo in Period 2	
Reporting group title	Placebo then OML 0.1%
Reporting group description:	
Treatment with placebo in Period 1, followed by OML 0.1% in Period 2	
Reporting group title	OML 0.15% then placebo
Reporting group description:	
Treatment with OML 0.15% in Period 1, followed by placebo in Period 2	
Reporting group title	Placebo then OML 0.15%
Reporting group description:	
Treatment with placebo in Period 1, followed by OML 0.15% in Period 2	
Reporting group title	OML 0.2% than placebo
Reporting group description:	
Treatment with OML 0.5% in Period 1, followed by placebo in Period 2	
Reporting group title	Placebo then OML 0.2%
Reporting group description:	
Treatment with placebo in Period 1, followed by OML 0.2% in Period 2	
Subject analysis set title	OML 0.1%, OML period
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
This analysis set included all patients receiving either OML 0.1% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.1% in Period 2. Data are included for the OML period.	
Subject analysis set title	OML 0.15%; OML period
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
This analysis set included all patients receiving either OML 0.15% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.15% in Period 2. Data are included for the OML period.	
Subject analysis set title	OML 0.2%; OML period

Subject analysis set type	Intention-to-treat

Subject analysis set description:

This analysis set included all patients receiving either OML 0.2% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.2% in Period 2. Data are included for the OML period.

Subject analysis set title	OML 0.1%; placebo period
Subject analysis set type	Intention-to-treat

Subject analysis set description:

This analysis set included all patients receiving either OML 0.1% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.1% in Period 2. Data from the placebo period are included.

Subject analysis set title	OML 0.15%; placebo period
Subject analysis set type	Intention-to-treat

Subject analysis set description:

This analysis set included all patients receiving either OML 0.15% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.15% in Period 2. Data are included for the placebo period.

Subject analysis set title	OML 0.2%; placebo period
Subject analysis set type	Intention-to-treat

Subject analysis set description:

This analysis set included all patients receiving either OML 0.2% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.2% in Period 2. Data are included for the placebo period.

Subject analysis set title	Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Patients receiving placebo

Subject analysis set title	OML 0.1%
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Patients receiving OML 0.15%

Subject analysis set title	OML 0.15%
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Patients receiving OML 0.15%

Subject analysis set title	OML 0.20%
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Patients receiving OML 0.2%

Primary: Bacterial count reduction factor in saliva

End point title	Bacterial count reduction factor in saliva

End point description:

The bacterial count reduction factor in saliva was defined as the absolute difference in log10 values of bacterial counts before and 1 min after rinsing, compared intra-individually. The mean of all intra-individually compared data was calculated for each treatment group separately. The mean of the treatment groups were compared between the application of OML and placebo on Visit 1 (Day 0) or Visit 3 (V2 + 14 or 21 days), respectively.

End point type	Primary

End point timeframe:

Bacterial count reduction factor in saliva over 4.5 days of treatment

End point values	OML 0.1%, OML period	OML 0.15%; OML period	OML 0.2%; OML period	OML 0.1%; placebo period
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	29	29	31	28
Units: Reduction factor				
arithmetic mean (standard deviation)	3.63 (± 2.11)	4.30 (± 2.06)	5.44 (± 2.02)	0.00 (± 0.70)

End point values	OML 0.15%; placebo period	OML 0.2%; placebo period		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	30	30		
Units: Reduction factor				
arithmetic mean (standard deviation)	0.06 (± 0.73)	0.05 (± 0.71)		

Statistical analyses

Statistical analysis title	Primary analysis; OML 0.1% vs placebo
Comparison groups	OML 0.1%; placebo period v OML 0.1%, OML period
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA

Statistical analysis title	Primary analysis; OML 0.15% vs placebo
Comparison groups	OML 0.15%; placebo period v OML 0.15%; OML period
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA

Statistical analysis title	Primary analysis; OML 0.2% vs placebo
Comparison groups	OML 0.2%; OML period v OML 0.2%; placebo period
Number of subjects included in analysis	61
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANOVA

Secondary: Plaque index, difference at Day 4

End point title	Plaque index, difference at Day 4

End point description:

Thickness and extension of plaque were assessed for the "Ramfjord teeth", for each of the 4 surfaces of the teeth, for the upper and lower jaw. The score ranges from 0 (no plaque) to 3 (abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin). The total mean plaque index was the sum of the individual grades divided by the number of investigated sites. The plaque index for each tooth was the sum of the 4 individual grades divided by 4. The total mean plaque index could range from 0 to 3 with higher indices indicating more plaque.

End point type	Secondary

End point timeframe:

After a rinsing period of 4 days

End point values	Placebo	OML 0.1%	OML 0.15%	OML 0.20%
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	88	29	30	31
Units: Score on a scale				
arithmetic mean (standard deviation)	1.58 (± 0.43)	0.52 (± 0.44)	0.43 (± 0.34)	0.42 (± 0.30)

Statistical analyses

No statistical analyses for this end point

Secondary: Gingival index, mean difference between 2 visits (rinsing period of 4 days)

End point title	Gingival index, mean difference between 2 visits (rinsing period of 4 days)

End point description:

After gingival bleeding was provoked, the gingival index (GI) was assessed for the upper and lower jaw, 4 sites (buccal, mesial, distal, lingual) of the "Ramfjord teeth", with the GI ranking from 0 to 3, with 0 for normal gingiva and 3 for severely inflammed gingiva. For each of the 4 sites a grade from 0 to 3 was given. The total mean GI was the sum of the individual grades divided by the number of investigated sites. The GI for each tooth was the sum of the 4 individual grades divided by 4. The total mean GI could range from 0 to 3 with higher indices indicating a worse gingival condition. The mean difference of GI between 2visits was assesed. Negative values indicate a worsening of the condition.

End point type	Secondary

End point timeframe:

Rinsing period of 4 days

End point values	Placebo	OML 0.1%	OML 0.15%	OML 0.20%
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	88	29	30	31
Units: Score on a scale				
arithmetic mean (standard deviation)	-0.24 (± 0.35)	0.00 (± 0.27)	0.14 (± 0.24)	0.12 (± 0.25)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected up to the last dose of study medication in Period 2 plus 14 days.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17

Reporting groups

Reporting group title	OML 0.1%, OML period

Reporting group description:

All patients receiving either OML 0.1% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.1% in Period 2. Data are included for the OML period.

Reporting group title	OML 0.1%; placebo period

Reporting group description:

All patients receiving either OML 0.1% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.1% in Period 2. Data from the placebo period are included.

Reporting group title	OML 0.15%; OML period

Reporting group description:

All patients receiving either OML 0.15% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.15% in Period 2. Data are included for the OML period.

Reporting group title	OML 0.15%; placebo period

Reporting group description:

All patients receiving either OML 0.15% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.15% in Period 2. Data are included for the placebo period.

Reporting group title	OML 0.2%; OML period

Reporting group description:

All patients receiving either OML 0.2% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.2% in Period 2. Data are included for the OML period.

Reporting group title	OML 0.2%; placebo period

Reporting group description:

All patients receiving either OML 0.2% in Period 1 followed by placebo in Period 2, or placebo in Period 1 followed by OML 0.2% in Period 2. Data are included for the placebo period.

Serious adverse events	OML 0.1%, OML period	OML 0.1%; placebo period	OML 0.15%; OML period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 30 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	OML 0.15%; placebo period	OML 0.2%; OML period	OML 0.2%; placebo period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	OML 0.1%, OML period	OML 0.1%; placebo period	OML 0.15%; OML period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 29 (41.38%)	6 / 29 (20.69%)	11 / 30 (36.67%)
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Burning sensation mucosal			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	1
Ageusia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Lymphadenopathy			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Device failure			

subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Breath odour			
subjects affected / exposed	0 / 29 (0.00%)	1 / 29 (3.45%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Gingival bleeding			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Aphthous stomatitis			
subjects affected / exposed	1 / 29 (3.45%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Tongue discolouration			
subjects affected / exposed	5 / 29 (17.24%)	0 / 29 (0.00%)	5 / 30 (16.67%)
occurrences (all)	5	0	5
Tooth discolouration			
subjects affected / exposed	7 / 29 (24.14%)	1 / 29 (3.45%)	6 / 30 (20.00%)
occurrences (all)	7	1	6
Dental caries			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Tooth deposit			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gingival inflammation			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in jaw			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	2 / 29 (6.90%)	2 / 29 (6.90%)	1 / 30 (3.33%)
occurrences (all)	2	2	1
Conjunctivitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 29 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	OML 0.15%; placebo period	OML 0.2%; OML period	OML 0.2%; placebo period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 30 (10.00%)	16 / 31 (51.61%)	4 / 31 (12.90%)
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Burning sensation mucosal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Ageusia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	1 / 30 (3.33%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Device failure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Breath odour			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	0	0	0
Aphthous stomatitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Tongue discolouration			
subjects affected / exposed	0 / 30 (0.00%)	10 / 31 (32.26%)	0 / 31 (0.00%)
occurrences (all)	0	10	0
Tooth discolouration			
subjects affected / exposed	1 / 30 (3.33%)	8 / 31 (25.81%)	0 / 31 (0.00%)
occurrences (all)	1	8	0
Dental caries			
subjects affected / exposed	1 / 30 (3.33%)	0 / 31 (0.00%)	0 / 31 (0.00%)
occurrences (all)	1	0	0
Tooth deposit			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Gingival inflammation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Pain in jaw			
subjects affected / exposed	0 / 30 (0.00%)	1 / 31 (3.23%)	0 / 31 (0.00%)
occurrences (all)	0	1	0

Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	2 / 31 (6.45%)	1 / 31 (3.23%)
occurrences (all)	0	2	1
Conjunctivitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 31 (0.00%)	1 / 31 (3.23%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None

Notes: