Clinical trial results:
Comparative efficacy of 3 different nicotine gum products to relieve urge for smoking (urge for nicotine) in healthy smokers

Summary

EudraCT number	2009-016679-31
Trial protocol	DK
Global end of trial date	28 May 2010

Results information

Result version number	v1 (current)
This version publication date	14 October 2021
First version publication date	14 October 2021

Trial information

Trial identification

Sponsor protocol code	F-DK109

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Fertin Pharma A/S
Sponsor organisation address	Dandyvej 19, Vejle, Denmark, 7100
Public contact	Birgitte Hyrup Andersen, Fertin Pharma A/S, bia@fertin.com
Scientific contact	Birgitte Hyrup Andersen, Fertin Pharma A/S, bia@fertin.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	16 October 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 May 2010
Global end of trial reached?	Yes
Global end of trial date	28 May 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare 2 test nicotine gum products and a reference nicotine gum product in abstinent smokers with regard to relief of urge for smoking and total nicotine abstinence symptoms after first dose

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 February 2010
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	Denmark: 35
Worldwide total number of subjects	35
EEA total number of subjects	35

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)	35
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening: objective examination, urinalysis (cannabis, morphine and cocaine), ECG, standard safety laboratory tests, and vital signs (blood pressure, pulse)

Period 1

Period 1 title	Period 1
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1 Gum A

Arm description:

This study was a 3-way cross-over study. In period 1, arm 1 received the test treatment Gum A, Fertin Pharma A/S 2 mg nicotine gum

Arm type	Experimental
Investigational medicinal product name	Fertin Pharma A/S 2 mg nicotine gum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Medicated chewing-gum
Routes of administration	Buccal use

Dosage and administration details:

The gum was chewed following a rhythm provided by a metronome (40 chew pr. minute) for 20 minutes

Arm title	Group 2 Gum B

Arm description:

This study was a 3-way cross-over study. In period 1, arm 2 received the test treatment Gum B, Fertin Pharma A/S 2 mg nicotine gum

Arm type	Experimental
Investigational medicinal product name	Fertin Pharma A/S 2 mg nicotine gum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Medicated chewing-gum
Routes of administration	Buccal use

Dosage and administration details:

The gum was chewed following a rhythm provided by a metronome (40 chew pr. minute) for 20 minutes

Number of subjects in period 1	Group 1 Gum A	Group 2 Gum B
Started	17	18
Completed	16	17
Not completed	1	1
Adverse event, non-fatal	1	1

Period 2

Period 2 title	Period 2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Reference product NF

Arm description:

This study was a 3-way cross-over study. In period 2, there was only one arm with all subjects receiving the reference product NF, Nicorette Freshmint® 2 mg nicotine gum

Arm type	Active comparator
Investigational medicinal product name	Nicorette Freshmint® 2 mg nicotine gum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Medicated chewing-gum
Routes of administration	Buccal use

Dosage and administration details:

The gum was chewed following a rhythm provided by a metronome (40 chew pr. minute) for 20 minutes

Number of subjects in period 2	Reference product NF
Started	33
Completed	33

Period 3

Period 3 title	Period 3
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1 Gum B

Arm description:

This study was a 3-way cross-over study. In period 3, arm 1 received the test treatment Gum B, Fertin Pharma A/S 2 mg nicotine gum

Arm type	Experimental
Investigational medicinal product name	Fertin Pharma A/S 2 mg nicotine gum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Medicated chewing-gum
Routes of administration	Buccal use

Dosage and administration details:

The gum was chewed following a rhythm provided by a metronome (40 chew pr. minute) for 20 minutes

Arm title	Group 2 Gum A

Arm description:

This study was a 3-way cross-over study. In period 3, arm 2 received the test treatment Gum A, Fertin Pharma A/S 2 mg nicotine gum

Arm type	Experimental
Investigational medicinal product name	Fertin Pharma A/S 2 mg nicotine gum
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Medicated chewing-gum
Routes of administration	Buccal use

Dosage and administration details:

The gum was chewed following a rhythm provided by a metronome (40 chew pr. minute) for 20 minutes

Number of subjects in period 3	Group 1 Gum B	Group 2 Gum A
Started	16	17
Completed	16	17

Baseline characteristics

End points

End points reporting groups

Reporting group title	Group 1 Gum A

Reporting group description:

This study was a 3-way cross-over study. In period 1, arm 1 received the test treatment Gum A, Fertin Pharma A/S 2 mg nicotine gum

Reporting group title	Group 2 Gum B

Reporting group description:

This study was a 3-way cross-over study. In period 1, arm 2 received the test treatment Gum B, Fertin Pharma A/S 2 mg nicotine gum

Reporting group title	Reference product NF

Reporting group description:

This study was a 3-way cross-over study. In period 2, there was only one arm with all subjects receiving the reference product NF, Nicorette Freshmint® 2 mg nicotine gum

Reporting group title	Group 1 Gum B

Reporting group description:

This study was a 3-way cross-over study. In period 3, arm 1 received the test treatment Gum B, Fertin Pharma A/S 2 mg nicotine gum

Reporting group title	Group 2 Gum A

Reporting group description:

This study was a 3-way cross-over study. In period 3, arm 2 received the test treatment Gum A, Fertin Pharma A/S 2 mg nicotine gum

Subject analysis set title	Gum A
Subject analysis set type	Full analysis

Subject analysis set description:

This set of subjects received the test product Gum A, Fertin Pharma A/S 2 mg nicotine

Subject analysis set title	Gum B
Subject analysis set type	Full analysis

Subject analysis set description:

This set of subjects received the test product Gum B, Fertin Pharma A/S 2 mg nicotine

Subject analysis set title	NF
Subject analysis set type	Full analysis

Subject analysis set description:

This set of subjects received the reference product, Nicorette Freshmint® 2 mg nicotine gum

Primary: Comparative analysis

End point title	Comparative analysis

End point description:

The primary objective was to compare 2 test nicotine gum products and a reference nicotine gum product in abstinent smokers with regard to relief of urge for smoking and total nicotine abstinence symptoms after first dose. The subjects' urge for smoking and abstinence symptoms were evaluated by questioning the subject. The questions concerned urge for smoking (urge for nicotine) and total nicotine abstinence symptoms and were rated by the subjects on a 100-mm visual analogue scale with words anchored at each end that expressed the 2 most extreme ratings. The efficacy was expressed by C max and AUC(0-35 minutes).

End point type	Primary

End point timeframe:

5-10 minutes before dosing and 2.5, 5.0, 7.5, 10.0, 12.5, 15.0, 17.5 20.0, 25.0, 30.0 and 35.0 minutes after dosing

End point values	Gum A	Gum B	NF	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	12	10	11	
Units: 100	12	10	11	

Statistical analyses

Statistical analysis title	AUC (0-35 min) A-NF
Comparison groups	Gum A v NF
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.05 [1]
Method	Regression, Linear

Notes:

[1] - The overall ability to relieve urge for smoking expressed as the mean AUC from 0 minutes to 35 minutes did not differ between Gum A versus Gum NF: p= 0.302

Statistical analysis title	AUC (0-35) B-NF
Comparison groups	Gum B v NF
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.05 [2]
Method	Regression, Linear

Notes:

[2] - The overall ability to relieve urge for smoking expressed as the mean AUC from 0 minutes to 35 minutes did not differ between Gum B versus Gum NF: p= 0.081

Statistical analysis title	C max (A-NF)
Comparison groups	NF v Gum A
Number of subjects included in analysis	23
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.05 [3]
Method	Regression, Linear

Notes:

[3] - Expressed by Cmax, Gum A compared with Gum NF showed a borderline statistically significant difference (p=0.0575)

Statistical analysis title	C max (B-NF)
Comparison groups	Gum B v NF

Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05 [4]
Method	Regression, Linear

Notes:

[4] - Expressed by Cmax, Gum B was more effective to relieve urge for smoking than Gum NF (p=0.0004)

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Subjects were monitored for adverse events on the days of dosing	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.0
Reporting groups	
Reporting group title	Gum A
Reporting group description: -	
Reporting group title	Gum B
Reporting group description: -	
Reporting group title	Reference product NF
Reporting group description: -	

Serious adverse events	Gum A	Gum B	Reference product NF
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 33 (0.00%)	0 / 33 (0.00%)	0 / 33 (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: 5 %

Non-serious adverse events	Gum A	Gum B	Reference product NF
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 33 (9.09%)	2 / 33 (6.06%)	0 / 33 (0.00%)
Gastrointestinal disorders			
Nausea			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 33 (9.09%)	2 / 33 (6.06%)	0 / 33 (0.00%)
occurrences (all)	3	2	0

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

None reported