



Clinical trial results:

Efficacy of smoking cessation with varenicline for e-cigarettes users: a randomized controlled trial (VAREVAPE)

Summary

EudraCT number	2016-000339-42
Trial protocol	IT
Global end of trial date	30 September 2020

Results information

Result version number	v2 (current)
This version publication date	07 January 2023
First version publication date	05 April 2022
Version creation reason	• New data added to full data set • Changes to summary attachments Wrong docs has been submitted during previous EUDRACT website updating
Summary attachment (see zip file)	RESULTS SU (REPORT VAREVAPE REVISED.doc) PREPRINT (MEDRXIV-2022-283715v1-Polosa.pdf)

Trial information

Trial identification

Sponsor protocol code	W1206810 Pfizer GRAND
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Pfizer
Sponsor organisation address	NEW YORK, NEW YORK, United States,
Public contact	NA, Pfizer, 1 800-438-1985, pfizercentreone@pfizer.com
Scientific contact	NA, NA, 1 800-438-1985, pfizercentreone@pfizer.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	31 August 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 September 2020
Global end of trial reached?	Yes
Global end of trial date	30 September 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study intends to evaluate the efficacy and safety of varenicline 1 mg BID in the cessation of smoking electronic cigarette (single users) or combined use, electronic and classical cigarette (dual users).

Protection of trial subjects:

Vital signs monitor

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 April 2018
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	Italy: 280
Worldwide total number of subjects	280
EEA total number of subjects	280

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)	280
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Made by social media

Pre-assignment

Screening details:

At screening visit, participants were seen in a screening visit, during which informed consent was obtained prior to any study procedures. Physical examination, blood pressure, pulse rate cardiological visit and electrocardiogram were done. A serum pregnancy test was completed for all females at the screening.

Period 1

Period 1 title	All time (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Varenicline

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Varenicline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Buccal use

Dosage and administration details:

0.5 mg

Arm title	Placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Buccal use

Dosage and administration details:

0.5 mg

Number of subjects in period 1	Varenicline	Placebo
Started	140	140
Completed	140	140

Baseline characteristics

End points

End points reporting groups

Reporting group title	Varenicline
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: vaping cessation

End point title	vaping cessation
End point description:	
End point type	Primary
End point timeframe:	
24 weeks	

End point values	Varenicline	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	140	140		
Units: numbers	140	140		

Statistical analyses

Statistical analysis title	sap
Statistical analysis description:	
Methods of Analysis	
Baseline and summary statistics will be calculated and reported for each treatment group. At baseline, differences between experimental and control groups will be evaluated by means of 1-way analysis of variance (ANOVA) for normally distributed continuous variables and by Mann-Whitney U-test for not normally distributed continuous variables; the χ^2 test of independence will be used for categorical variables. Secondary endpoints will be analyzed using procedures similar	
Comparison groups	Varenicline v Placebo
Number of subjects included in analysis	280
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANOVA

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

3 months

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1
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Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: Not revealed during the study

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