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	31 March 2020

Results information

Result version number	v1
This version publication date	05 April 2022
First version publication date	05 April 2022
Summary attachment (see zip file)	Results (REPORT VAREVAPE MARCH 2021.doc)

Trial information

Trial identification

Sponsor protocol code	W1206810

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Unict: Unict

Notes:

Sponsors

Sponsor organisation name	Centro Prevenzione Cura Tabagismo
Sponsor organisation address	via Santa Sofia Catania, Catania, Italy,
Public contact	Medicina Interna, Centro per la prevenzione e cura tabagismo, AOU Policlinico Vittorio Emanuele- Università di Catania, 0039 0953781537, cpctunict@gmail.com
Scientific contact	Medicina Interna, Centro per la prevenzione e cura tabagismo, AOU Policlinico Vittorio Emanuele- Università di Catania, 0039 0953781537, cpctunict@gmail.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 March 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2020
Global end of trial reached?	Yes
Global end of trial date	31 March 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 be 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	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Arm title	Varenicline plus Motivational Interviewing

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

Number of subjects in period 1	Varenicline plus Motivational Interviewing
Started	280
Completed	280

Baseline characteristics

End points

End points reporting groups

Reporting group title	Varenicline plus Motivational Interviewing

Reporting group description: -

Primary: vaping cessation

End point title	vaping cessation[1]

End point description:

End point type	Primary

End point timeframe:

24 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: "Validate full set data"

End point values	Varenicline plus Motivational Interviewing			
Subject group type	Reporting group			
Number of subjects analysed	280			
Units: numbers	280			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 3 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

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: "Validate full set data"

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