



Clinical trial results:

EUROACTION PLUS: Intensive smoking intervention (Varenicline) during a preventive cardiology programme for patients with established atherosclerotic disease, people at high cardiovascular risk and their families

Summary

EudraCT number	2009-012451-18
Trial protocol	GB ES NL
Global end of trial date	31 July 2011

Results information

Result version number	v1 (current)
This version publication date	02 January 2020
First version publication date	02 January 2020

Trial information

Trial identification

Sponsor protocol code	CRO1202
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Additional study identifiers

ISRCTN number	ISRCTN22073647
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	South Kensington Campus, London, United Kingdom, SW7 2AZ
Public contact	Professor David Wood, Imperial College London, +44 (0)20 8846 7352, d.wood@imperial.ac.uk
Scientific contact	Professor David Wood, Imperial College London, +44 (0)20 8846 7352, d.wood@imperial.ac.uk

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	10 January 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 December 2010
Global end of trial reached?	Yes
Global end of trial date	31 July 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate whether VARENICLINE prescribed to patients enrolled to a preventive cardiology programme can achieve faster, more effective smoking cessation in patients with coronary or other atherosclerotic disease, people at high cardiovascular risk and their partners in every day clinical practice.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2009
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	Netherlands: 105
Country: Number of subjects enrolled	Spain: 173
Country: Number of subjects enrolled	United Kingdom: 232
Country: Number of subjects enrolled	Italy: 186
Worldwide total number of subjects	696
EEA total number of subjects	696

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)	341
From 65 to 84 years	355

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

A multi-center parallel-group randomized controlled trial (RCT) was conducted in 20 General Practice across Italy, Spain, the Netherlands, and the UK.

Patients were randomized individually within practices to participate in the EUROACTION intervention program.

Pre-assignment

Screening details:

The trial started in October 2009 and was completed in July 2011. Persistent smokers (men and women) with vascular disease or at high cardiovascular risk were identified from the practice register

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Euroaction Plus (EU+)
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Champix
Investigational medicinal product code	Varenicline Tartrate
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Varenicline will be introduced within the first 4 weeks after baseline assessment and will be initiated 1 week before the patient's chosen quit date. The dose of varenicline will be titrated as follows: 0.5 mg for days 1 to 3, 0.5 mg twice per day on days 4 to 7, then 1 mg twice per day through week 12. The target quit date will be within 4 weeks of starting varenicline.

Arm title	Usual Care (UC)
Arm description: -	
Arm type	usual care products
Investigational medicinal product name	Usual care
Investigational medicinal product code	Varenicline Tartrate
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

16 weeks

Number of subjects in period 1	Euroaction Plus (EU+)	Usual Care (UC)
Started	350	346
Completed	342	341
Not completed	8	5
no data available	8	5

Baseline characteristics

Reporting groups

Reporting group title	Euroaction Plus (EU+)
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Reporting group description: -

Reporting group title	Usual Care (UC)
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Reporting group description: -

Reporting group values	Euroaction Plus (EU+)	Usual Care (UC)	Total
Number of subjects	350	346	696
Age categorical			
Units: Subjects			
Aged < 60 years	176	165	341
Aged > 60 years	174	181	355
Age continuous			
Units: years			
arithmetic mean	59.6	60.4	
standard deviation	± 6.2	± 7.0	-
Gender categorical			
Units: Subjects			
Female	144	137	281
Male	206	209	415

End points

End points reporting groups

Reporting group title	Euroaction Plus (EU+)
Reporting group description: -	
Reporting group title	Usual Care (UC)
Reporting group description: -	

Primary: Percent of the participants who quit smoking

End point title	Percent of the participants who quit smoking
End point description: Self-reported abstinence from smoking - 7-day point (period) prevalence of non-smoking Bedfont Micro + Smokerlyzer Breath carbon monoxide (CO), 10 parts per million	
End point type	Primary
End point timeframe: 16 weeks	

End point values	Euroaction Plus (EU+)	Usual Care (UC)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	342	341		
Units: Percent	52	19		

Statistical analyses

Statistical analysis title	Quit smoking
Comparison groups	Euroaction Plus (EU+) v Usual Care (UC)
Number of subjects included in analysis	683
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01
Method	Regression, Logistic

Secondary: Percent of the participants who eat Fruit and vegetables ≥ 400 g/day

End point title	Percent of the participants who eat Fruit and vegetables ≥ 400 g/day
End point description:	
End point type	Secondary
End point timeframe: 16 weeks	

End point values	Euroaction Plus (EU+)	Usual Care (UC)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	285	261		
Units: Number of participants	22	18		

Statistical analyses

Statistical analysis title	Fruit and vegetables ≥ 400 g/day
Comparison groups	Euroaction Plus (EU+) v Usual Care (UC)
Number of subjects included in analysis	546
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.27
Method	Regression, Logistic

Secondary: Percent of participants who eat Fish ≥ 20 g/day or oily fish ≥ 3 x/week

End point title	Percent of participants who eat Fish ≥ 20 g/day or oily fish ≥ 3 x/week
End point description:	
End point type	Secondary
End point timeframe:	
16 weeks	

End point values	Euroaction Plus (EU+)	Usual Care (UC)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	285	261		
Units: Percent of participants	64	55		

Statistical analyses

Statistical analysis title	Fish ≥ 20 g/day or oily fish ≥ 3 x/week
Comparison groups	Euroaction Plus (EU+) v Usual Care (UC)

Number of subjects included in analysis	546
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.02
Method	Regression, Logistic

Secondary: Percent of participants who consume Alcohol ≤ 30 g/day

End point title	Percent of participants who consume Alcohol ≤ 30 g/day
End point description:	
End point type	Secondary
End point timeframe:	
16 weeks	

End point values	Euroaction Plus (EU+)	Usual Care (UC)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	279	255		
Units: Percent of participants	87	80		

Statistical analyses

Statistical analysis title	Alcohol ≤ 30 g/day
Comparison groups	Euroaction Plus (EU+) v Usual Care (UC)
Number of subjects included in analysis	534
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.04
Method	Regression, Logistic

Secondary: Participnats with Mediterranean diet score ≥ 9

End point title	Participnats with Mediterranean diet score ≥ 9
End point description:	
End point type	Secondary
End point timeframe:	
16 weeks	

End point values	Euroaction Plus (EU+)	Usual Care (UC)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	285	260		
Units: Percent of participants	52	37		

Statistical analyses

Statistical analysis title	Mediterranean diet score ≥ 9
Comparison groups	Euroaction Plus (EU+) v Usual Care (UC)
Number of subjects included in analysis	545
Analysis specification	Post-hoc
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic

Secondary: ≥ 30 min physical activity moderate intensity at least 5 x/week

End point title	≥ 30 min physical activity moderate intensity at least 5 x/week
End point description:	≥ 30 min physical activity moderate intensity at least 5 x/week Or $\geq 3 \times 20$ min vigorous activity/week
End point type	Secondary
End point timeframe:	16 weeks

End point values	Euroaction Plus (EU+)	Usual Care (UC)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	284	263		
Units: Percent of participants	16	7		

Statistical analyses

Statistical analysis title	≥ 30 min physical activity moderate intensity
Comparison groups	Euroaction Plus (EU+) v Usual Care (UC)
Number of subjects included in analysis	547
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.002
Method	Regression, Logistic

Secondary: Percent of participants with Ideal BMI (25 kg/m2)

End point title	Percent of participants with Ideal BMI (25 kg/m2)
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End point description:

End point type	Secondary
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End point timeframe:

16 weeks

End point values	Euroaction Plus (EU+)	Usual Care (UC)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	290	285		
Units: Percent of participants	23	32		

Statistical analyses

Statistical analysis title	Ideal BMI (25 kg/m2)
Comparison groups	Euroaction Plus (EU+) v Usual Care (UC)
Number of subjects included in analysis	575
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.02
Method	Regression, Logistic

Secondary: Percent of participants with SBP/DBP ,130/80 mmHg

End point title	Percent of participants with SBP/DBP ,130/80 mmHg
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End point description:

End point type	Secondary
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End point timeframe:

16 weeks

End point values	Euroaction Plus (EU+)	Usual Care (UC)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	296	285		
Units: Percent of participants	33	25		

Statistical analyses

Statistical analysis title	SBP/DBP ,130/80 mmHg
Comparison groups	Euroaction Plus (EU+) v Usual Care (UC)
Number of subjects included in analysis	581
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.02
Method	Regression, Logistic

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

16 weeks

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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Reporting groups

Reporting group title	Euroaction Plus (EU+)
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Reporting group description: -

Reporting group title	Usual Care (UC)
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Reporting group description: -

Serious adverse events	Euroaction Plus (EU+)	Usual Care (UC)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 350 (0.00%)	0 / 346 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Euroaction Plus (EU+)	Usual Care (UC)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 350 (0.00%)	0 / 346 (0.00%)	

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: No adverse event was reported.

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.

The investigators were only able to evaluate the outcomes at the end of our 16 weeks nurse-led programme and whether abstinence from tobacco, a healthier lifestyle and risk factor control achieved are sustained to 1 year remains an open question.
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Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/24616337>