DECLARATION OF CONFLICT OF INTEREST

EUROACTION PLUS

Funded by an Independent Investigator Grant from Pfizer
EUROACTION preventive cardiology programme *plus* intensive smoking cessation with *Varenicline*

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Imperial College London, United Kingdom

ESC Congress, Paris, France
August 28th to 31st 2011
EUROACTION PLUS

Aim

The aim was to determine in high medical risk smokers if a nurse-led, family based preventive cardiology programme (EUROACTION), with an intensive smoking intervention including optional use of Varenicline, could achieve greater smoking abstinence and improved lifestyle and risk factor control in vascular patients, people at high risk of developing atherosclerotic disease, and the partners of both, in everyday clinical practice.
EUROACTION + Intensive Smoking Cessation with Varenicline

UK

Italy

Netherlands

Spain

Imperial College London
Study Population

Vascular patients and partners

Patients (18 – 80 years) with a new or recurrent diagnosis of coronary or other atherosclerotic disease, and who are smokers

High vascular risk people and partners

Men and women (50 - 80 years) at high multifactorial risk (hypertension/dyslipidaemia/diabetes) and who are smokers
Study Design

20 General Practices

Randomisation of individuals

INTERVENTION

USUAL CARE

Initial Assessment

PATIENTS

PARTNERS

PARTNERS

PARTNERS

Intervention

PROGRAMME

16 weeks

16 weeks assessment

PATIENTS

PARTNERS

PATIENTS

PARTNERS
The EUROACTION PLUS preventive cardiology programme

A nurse led multidisciplinary family based programme for vascular patients, high risk individuals and their partners

- Focus on smoking cessation
- Optional Varenicline to assist quit attempts
- Comprehensive lifestyle and risk factor management

Imperial College
London
Smoking Cessation Management

Varenicline

Start: 1 week before the patient’s chosen quit date

Titration:
0.5 mg: days 1 to 3
0.5 mg twice per day: days 4 to 7
1 mg twice per day: trough week 12

Target quit date: within 4 weeks of starting Varenicline
Intention to treat analysis based on all people having a 16-week assessment
Outcome Measures

- Primary Endpoint

  7-day point (period) prevalence of non-smoking validated by breath CO (< 10 ppm) at 16 weeks
Secondary Outcomes

Proportions of patients achieving European and national lifestyle, risk factors and therapeutic targets for cardiovascular disease prevention:

- Diet/ nutrition (Food Habit Questionnaire, Mediterranean Diet Score)
- Physical activity (7-day PAR, Pedometer, Chester step test, DASI physical activity questionnaire)
- Overweight/ obesity (body mass index (BMI), waist circumference)
Study Participants

N=696 Eligible patients
  N=559 High-Risk patients
  N=137 Vascular patients

EA+ ARM
N=350 patients
  N=276 High-Risk patients
  N=74 Vascular patients

N=328 Baseline assessment
N=313 Participated in EA+

N=299 85.4%
16-weeks assessment

N=346 Primary endpoint

USUAL CARE ARM
N=346 patients
  N=283 High-Risk patients
  N=63 Vascular patients

N=288 83.2%
16-weeks assessment

N=335 Primary endpoint
## Distribution of patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Usual Care N=346</th>
<th>EuroAction+ N=350</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age</strong></td>
<td>60.4 yrs</td>
<td>59.6 yrs</td>
</tr>
<tr>
<td><strong>Aged &lt; 60 years</strong></td>
<td>47.6%</td>
<td>51.1%</td>
</tr>
<tr>
<td><strong>Women</strong></td>
<td>39.6%</td>
<td>41.1%</td>
</tr>
<tr>
<td><strong>Vascular patient</strong></td>
<td>18.2%</td>
<td>21.1%</td>
</tr>
<tr>
<td><strong>Low education</strong></td>
<td>26.6%</td>
<td>25.3%</td>
</tr>
<tr>
<td><strong>Not employed</strong></td>
<td>43.5%</td>
<td>44.0%</td>
</tr>
<tr>
<td><strong>Centre</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>15.3%</td>
<td>14.9%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>25.4%</td>
<td>24.3%</td>
</tr>
<tr>
<td>Spain</td>
<td>32.7%</td>
<td>34.0%</td>
</tr>
<tr>
<td>UK</td>
<td>26.6%</td>
<td>26.9%</td>
</tr>
</tbody>
</table>

*primary school or less; **unemployed, house person or retired
Smoking abstinence for last 7 days confirmed by breath CO <10ppm

PRIMARY ENDPOINT

Odds Ratio (95% CI) = 4.52 (3.20 to 6.39)
Smoking abstinence for last 7 days confirmed by breath CO <10 ppm

**PRIMARY ENDPOINT**

<table>
<thead>
<tr>
<th>Category</th>
<th>EA+</th>
<th>UC</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>51.2%</td>
<td>18.8%</td>
</tr>
<tr>
<td>Vascular patients</td>
<td>48.6%</td>
<td>20.0%</td>
</tr>
<tr>
<td>High Risk patients</td>
<td>51.8%</td>
<td>18.6%</td>
</tr>
<tr>
<td>Italy</td>
<td>51.9%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>57.8%</td>
<td>29.8%</td>
</tr>
<tr>
<td>Spain</td>
<td>53.0%</td>
<td>17.1%</td>
</tr>
<tr>
<td>UK</td>
<td>42.6%</td>
<td>13.3%</td>
</tr>
<tr>
<td>Male</td>
<td>53.2%</td>
<td>22.7%</td>
</tr>
<tr>
<td>Female</td>
<td>48.2%</td>
<td>12.9%</td>
</tr>
<tr>
<td>Aged &lt; 60 years</td>
<td>50.8%</td>
<td>16.4%</td>
</tr>
<tr>
<td>Aged ≥ 60 years</td>
<td>51.5%</td>
<td>21.0%</td>
</tr>
</tbody>
</table>

Odds Ratio (95% CI)
Smoking abstinence for last 7 days confirmed by breath CO <10 ppm

**PRIMARY ENDPOINT**

- **Usual Care arm**: 18.8% (N=335)
- **Intervention arm Not participated**: 14.7% (N=34)
- **Intervention arm Participated Not completed**: 16.7% (N=24)
- **Intervention arm Participated Completed**: 62.4% (N=266)
Smoking abstinence for last 7 days confirmed by breath CO <10 ppm

PRIMARY ENDPOINT IN PARTNERS (n=108)

Odds Ratio (95% CI) = 4.67 (1.92 to 11.48)
Diet

- Mediterranean Score ≥ 9
  - Usual Care: 37%
  - EuroAction+: 52%
  - Change: +15.0%
    - +6.7% to +23.2%

- Fish ≥ 20 g/day or oily fish ≥ 3 x/week
  - Usual Care: 55%
  - EuroAction+: 64%
  - Change: +9.4%
    - +1.2% to +17.6%

- Fruit & Veg ≥ 400 g/day
  - Usual Care: 18%
  - EuroAction+: 22%
  - Change: +3.7%
    - -2.9% to +10.4%

- Alcohol ≤ 30 g/day
  - Usual Care: 80%
  - EuroAction+: 87%
  - Change: +6.3%
    - +0.1% to +12.7%
On Target*

- Usual Care: 7%
- EuroAction+: 16%

Difference:
- EuroAction+: +9.0% (3.7% to +14.3%)

DASI score ≥ 25

- Usual Care: 83%
- EuroAction+: 89%

Difference:
- EuroAction+: +5.5% (-0.3% to +11.4%)

Daily steps ≥ 7500

- Usual Care: 34%
- EuroAction+: 42%

Difference:
- EuroAction+: +8.4% (-1.1% to +17.8%)

Chester Step Test

- Usual Care: 27%
- EuroAction+: 38%

Difference:
- EuroAction+: +10.5% (+0.5% to +20.4%)

* 30 minutes of aerobic exercise at moderate intensity ≥ 5 times/week or 20 minutes of vigorous activity on ≥ 3 days/week

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**Physical Activity**

- Usual Care
- EuroAction+
Blood Pressure

- **SBP/DBP < 140/90 mmHg**: 43% in Usual Care, 52% in EuroAction+. Increase of +9.5% from baseline, +1.2% to +17.9%.
- **AH drug use**: 53% in Usual Care, 51% in EuroAction+. Decrease of -1.3% from baseline, -9.5% to +6.8%.
- **Therapeutic control of BP**: 37% in Usual Care, 42% in EuroAction+. Increase of +4.9% from baseline, -6.6% to +16.4%.

CVD: Cardiovascular Disease.
Serum Lipids

**TC < 4.5 mmol/l**
- Usual Care: 19%
- EuroAction+: 14%

**LDL < 2.5 mmol/l**
- Usual Care: 18%
- EuroAction+: 17%

**HDL ≥ 1 mmol/l**
- Usual Care: 85%
- EuroAction+: 82%

**TG < 1.7 mmol/l**
- Usual Care: 61%
- EuroAction+: 61%

- TC < 4.5 mmol/l CVD: -4.5%
- LDL < 2.5 mmol/l CVD: -0.4%
- HDL ≥ 1 mmol/l: -2.9%
- TG < 1.7 mmol/l: +0.4%
Psychosocial Characteristics

- **HADS Anxiety score < 8**
  - Usual Care: 73%
  - EuroAction+: 74%
  - Change: +0.3%
  - Range: -7.1% to +7.7%

- **HADS Depression score < 8**
  - Usual Care: 81%
  - EuroAction+: 81%
  - Change: +0.8%
  - Range: -5.8% to +7.4%

- **EQ-5D VAS score > 75**
  - Usual Care: 36%
  - EuroAction+: 48%
  - Change: +12.0%
  - Range: +3.8% to +20.2%
Conclusions

- This nurse-led EUROACTION+ preventive cardiology programme reduced smoking by half in high risk patients.
- Smoking cessation was also significantly higher in the partners.
- Patients achieved a healthier diet, increased physical activity levels with no significant increase in weight.
- Blood pressure control was better.
- Quality of life improved.
Co-ordinating and Data Management Centre

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EUROACTION PLUS

Sponsorship

Independent Investigator Grant from Pfizer pharmaceuticals to Imperial College London