AGNELLI 2003

A randomised clinical trial investigating the effect of warfarin versus discontinuation in patients who had had 3 months of oral anticoagulant therapy without experiencing recurrence or bleeding after a first episode of pulmonary embolism.

1 Treatments

- **Studied treatment**: continuation for 3 or 9 additional months of warfarin or other oral anticoagulant was adjusted to achieve a target INR between 2.0 and 3.0.

- **Control treatment**: discontinuation (after 3 months)

- **Concomitant treatments**: -

2 Patients

- **Patients**: patients who had had 3 months of oral anticoagulant therapy without experiencing recurrence or bleeding after a first episode of pulmonary embolism.

- **Inclusion criteria**: patients ranging from 15 to 85 years of age with a first episode of symptomatic, objectively confirmed pulmonary embolism who had completed 3 uninterrupted months of oral anticoagulant therapy without having a recurrence of bleeding.

- **Exclusion criteria**: prolonged anticoagulant therapy for reasons other than venous thromboembolism; major psychiatric disorders; life expectancy shorter than two years;

3 Methods

- **Blinding**: open

- **Design**: Parallel groups

- **Centers**: 19

- **Geographical area**: Italy

- **Sample size**: -18 (-9 / -9)

- **ArretTrt1**: -

- **ArretTrt0**: -

- **PeriodeInclusion**: -

- **Hypothese**: -
## 4 Results

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
<th>d</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVT</td>
<td>-/-9</td>
<td>-/-9</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>PE (with or without DVT)</td>
<td>-/-9</td>
<td>-/-9</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>Incidence of recurrent VTE</td>
<td>15/165</td>
<td>18/161</td>
<td>0.81</td>
<td>[0.39; 1.67]</td>
</tr>
<tr>
<td>Incidence of recurrent VTE (65279; period after cessation of study medication until end of follow-up)</td>
<td>-/-9</td>
<td>-/-9</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>Mortality</td>
<td>12/165</td>
<td>7/161</td>
<td>1.67</td>
<td>[0.64; 4.36]</td>
</tr>
<tr>
<td>Incidence of major bleeding</td>
<td>3/165</td>
<td>1/161</td>
<td>2.93</td>
<td>[0.30; 28.44]</td>
</tr>
<tr>
<td>Incidence of major bleeding (65279; period after cessation of study medication until end of follow-up)</td>
<td>-/-9</td>
<td>-/-9</td>
<td>NA</td>
<td>-</td>
</tr>
</tbody>
</table>

## 5 References


## 6 Comments