PLATO 2009

NCT00391872

1 Treatments

Studied treatment  ticagrelor 90mg twice daily
oral loading dose of ticagrelor 180 mg

Control treatment  clopidogrel 75mg once daily
oral loading dose of clopidogrel 300 mg

Concomittant treatments  All patients received acetylsalicylic acid (aspirin) at a dose of 75 to 100 mg daily unless they could not tolerate the drug.

Age (mean), years  62y (median)

temale (%)  28.3%

2 Patients

Patients  patients with an acute coronary syndrome, with or without ST-segment elevation (onset of symptoms within the previous 24h).

Inclusion criteria  acute coronary syndrome, with or without ST-segment elevation, with an onset of symptoms during the previous 24 hours;

Exclusion criteria  contraindication to clopidogrel; fibrinolytic therapy within 24 hours before; need for oral anticoagulation therapy; increased risk of bradycardia; concomitant therapy with a strong cytochrome P-450 3A inhibitor or inducer

BMI (median)  27 (13-70)

history of MI (%)  20.5%

3 Methods

Blinding  double blind

Design  Parallel groups

Centers  862

Geographical area  43 countries

Sizes  9333/9291

node status  -

Positive troponin I  85.7%
ST-elevation MI 37.8%
Non–ST-elevation MI 42.7%

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>vascular death, MI, stroke</td>
<td>864/9333</td>
<td>1014/9291</td>
<td>0.85</td>
<td>[0.77; 0.93]</td>
</tr>
<tr>
<td>death, MI, stroke</td>
<td>901/9333</td>
<td>1065/9291</td>
<td>0.84</td>
<td>[0.77; 0.92]</td>
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<tr>
<td>Severe recurrent ischemia</td>
<td>302/9333</td>
<td>345/9291</td>
<td>0.87</td>
<td>[0.74; 1.02]</td>
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<tr>
<td>Ischemic stroke</td>
<td>96/9333</td>
<td>91/9291</td>
<td>1.05</td>
<td>[0.79; 1.40]</td>
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<tr>
<td>Hemorrhagic stroke</td>
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<td>13/9291</td>
<td>1.76</td>
<td>[0.89; 3.48]</td>
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<td>cardiovascular events</td>
<td>864/9333</td>
<td>1014/9291</td>
<td>0.85</td>
<td>[0.77; 0.93]</td>
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<tr>
<td>refractory ischemia</td>
<td>/9333</td>
<td>/9291</td>
<td>NA</td>
<td>-</td>
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<td>Vasc events</td>
<td>1290/9333</td>
<td>1456/9291</td>
<td>0.88</td>
<td>[0.81; 0.96]</td>
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<tr>
<td>Non vasc deaths</td>
<td>46/9333</td>
<td>64/9291</td>
<td>0.72</td>
<td>[0.49; 1.05]</td>
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<td>all cause death</td>
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<td>506/9291</td>
<td>0.78</td>
<td>[0.69; 0.90]</td>
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<td>Non-fatal MI</td>
<td>/9333</td>
<td>/9291</td>
<td>NA</td>
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<td>fatal and non fatal MI</td>
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<td>593/9291</td>
<td>0.85</td>
<td>[0.75; 0.96]</td>
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<tr>
<td>Non-fatal stroke</td>
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<td>/9291</td>
<td>NA</td>
<td>-</td>
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<td>revascularization</td>
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<td>/9291</td>
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<td>-</td>
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<tr>
<td>fatal and non fatal stroke</td>
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<td>106/9291</td>
<td>1.17</td>
<td>[0.90; 1.52]</td>
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<td>Vasc deaths</td>
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<td>0.80</td>
<td>[0.69; 0.92]</td>
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<td>fatal bleeding</td>
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<td>[0.48; 1.58]</td>
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<td>Major bleeds</td>
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<td>638/9291</td>
<td>1.03</td>
<td>[0.92; 1.15]</td>
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<td>all bleeding (major and minor)</td>
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<td>906/9291</td>
<td>1.04</td>
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5 References