REPLACE 2001

A randomised clinical trial investigating the effect of telmisartan versus enalapril in ambulatory patients at least 21 years of age, in sinus rhythm, with chronic moderate-symptomatic heart failure (New York Heart Association class II–III) and a left ventricular ejection fraction of 40% or lower

1 Treatments

<table>
<thead>
<tr>
<th>Studied treatment</th>
<th>Telmisartan, 10 mg, 20 mg, 40 mg, 80 mg daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control treatment</td>
<td>Enalapril, 10 mg twice daily</td>
</tr>
</tbody>
</table>

Concomittant treatments -

2 Patients

<table>
<thead>
<tr>
<th>Patients</th>
<th>ambulatory patients at least 21 years of age, in sinus rhythm, with chronic moderate-symptomatic heart failure (New York Heart Association class II–III) and a left ventricular ejection fraction of 40% or lower</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion criteria</td>
<td>-</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td>any life-threatening disease (cancer, hemodynamically significant pulmonary embolism, AIDS, etc.), clinically significant stenotic valvular disease, aortic or mitral regurgitation, or hypertrophic or restrictive cardiomyopathy, a history of myocardial infarction, unstable angina, syncopal episodes, or surgery within 6 months of the study; fever, primary renal, hepatic, or metabolic diseases, and those requiring treatment with phosphodiesterase inhibitors, dopamine or beta-agonists (e.g. ibopamine), class I antiarrhythmic agents, or chronic administration of high doses of non-steroidal anti-inflammatory drugs or acetaminophen. Women of child-bearing potential</td>
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</tbody>
</table>
## 3 Methods

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Blinding</strong></td>
<td>Double blind</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>Parallel groups</td>
</tr>
<tr>
<td><strong>Centers</strong></td>
<td>multicentre</td>
</tr>
<tr>
<td><strong>Geographical area</strong></td>
<td>-</td>
</tr>
<tr>
<td><strong>Sample size</strong></td>
<td>378 (301 / 77)</td>
</tr>
<tr>
<td><strong>ArretTrt1</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>ArretTrt0</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>PeriodeInclusion</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Hypothese</strong></td>
<td>NA</td>
</tr>
</tbody>
</table>
4 Results

Endpoint

dead or CV hospitalization
Sudden death or resuscitated cardiac arrest
all cause death or hospital admission
hospital admission for heart failure
hospital admission for any reason
Cardiovascular death or hospital admission for CHF
Cardiovascular death
Death from Any Cause, Cardiac Arrest with Resuscitation, Hospitalization for Worsening Heart Failure, or Therapy with Intravenous Inotropes or Vasodilators
all cause death
prostate cancer
breast cancer
cancer death
cancer
cancer (prespecified as endpoint)
lung cancer
Cough
Any adverse event
Adverse effect leading to treatment discontinuation
Angioedema
Hypotension
Hyperkalaemia
Increase in creatinine

5 References

Dunselman PH Effects of the replacement of the angiotensin converting enzyme inhibitor enalapril by the angiotensin II receptor blocker telmisartan in patients with congestive heart failure. The replacement of angiotensin converting enzyme inhibition (REPLACE) investigators. Int J Cardiol 2001 Feb;77:131-8; discussion 139-40 [1182175]

6 Comments