# ixCELL-DCM 2016

**NCT01670981**

A randomised clinical trial investigating the effect of ixmyelocel-T versus placebo in patients with New York Heart Association class III or IV symptomatic heart failure due to ischaemic dilated cardiomyopathy, who had left ventricular ejection fraction 35% or less, an automatic implantable cardioverter defibrillator, and who were ineligible for revascularisation procedures.

## 1 Treatments

<table>
<thead>
<tr>
<th>Studied treatment</th>
<th>ixmyelocel-T expanded, multicellular therapy produced from a patient’s own bone marrow by selectively expanding two key types of bone marrow mononuclear cells: CD90+ mesenchymal stem cells and CD45+ CD14+ auto-fluorescent+ activated macrophages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control treatment</td>
<td>placebo</td>
</tr>
</tbody>
</table>

## 2 Patients

<table>
<thead>
<tr>
<th>Patients</th>
<th>patients with New York Heart Association class III or IV symptomatic heart failure due to ischaemic dilated cardiomyopathy, who had left ventricular ejection fraction 35% or less, an automatic implantable cardioverter defibrillator, and who were ineligible for revascularisation procedures</th>
</tr>
</thead>
</table>

## 3 Methods

<table>
<thead>
<tr>
<th>Blinding</th>
<th>-</th>
<th>20pt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>-</td>
<td>20pt</td>
</tr>
<tr>
<td>Centers</td>
<td>-</td>
<td>20pt</td>
</tr>
<tr>
<td>Geographical area</td>
<td>-</td>
<td>20pt</td>
</tr>
<tr>
<td>Sample size</td>
<td>126 ( 60 / 66 )</td>
<td>20pt</td>
</tr>
<tr>
<td>ArretTrt1</td>
<td>-</td>
<td>20pt</td>
</tr>
<tr>
<td>ArretTrt0</td>
<td>-</td>
<td>20pt</td>
</tr>
<tr>
<td>PeriodInclusion</td>
<td>-</td>
<td>20pt</td>
</tr>
<tr>
<td>Hypothese</td>
<td>-</td>
<td>20pt</td>
</tr>
</tbody>
</table>
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>acute heart failure</td>
<td>-/60</td>
<td>-/66</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>ventricular tachycardia</td>
<td>-/60</td>
<td>-/66</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>NYHA deterioration</td>
<td>-/60</td>
<td>-/66</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>cardiac event</td>
<td>-/60</td>
<td>-/66</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>all-cause mortality</td>
<td>-/60</td>
<td>-/66</td>
<td>NA</td>
<td>-</td>
</tr>
</tbody>
</table>

5 References


6 Comments