Are Stem Cell Treatments Safe? This Study Sheds Light

**Purpose of Study:***
To determine if stem cell injections are safe when used for orthopedic degenerative conditions or injuries.

**Methodology:**
The study included 2,372 patients who received mesenchymal stem cell (MSC) injections, with a focus on orthopedic surgical procedures (e.g., total knee arthroplasty). The study followed patients for up to 3 months post-treatment, with adverse events (AEs) and serious adverse events (SAEs) reported.

**Results:**
- In total, 325 adverse events were reported, with 10 possible SAEs reported.
- The most common AEs were post-procedure pain and other pain-related conditions, totaling 29% of all reported AEs.
- The AE rates for different treatment groups were as follows:
  - **SD** (stem cell injection only): 1.9%
  - **AD** (injection with adipose tissue): 1.5%
  - **CE** (injection with culture-expanded MSCs): 1.6%

**No Clinical Evidence Linking MSCs with Increased Risk of Cancer:**
The study found no evidence linking MSCs with an increased risk of cancer, despite a lack of clinical evidence to the contrary.

**Study Conclusions:**
- The study supports the safety of MSC treatments for orthopedic conditions.
- Further research is needed to confirm these findings in larger and longer follow-up studies.
- The study was designed to be a safety study of MSC and MSC injections for the treatment of orthopedic conditions in a larger population.

**Additional Information:**

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**Study Facts**
- **Purpose:** Investigate stem cell safety for orthopedic procedures.
- **Patients:** 2,372 orthopedic patients.
- **Follow-up:** Up to 3 months post-treatment.
- **AEs:** 325 reported.
- **SAEs:** 10 reported.

**Study Methods**
- **Treatment Groups:**
  - **SD** (stem cell injection only): 1.9%
  - **AD** (injection with adipose tissue): 1.5%
  - **CE** (injection with culture-expanded MSCs): 1.6%

**Study Subjects**
- **Population:** 3,012 orthopedic patients.
- **Sex:**
  - **Male:** 57%
  - **Female:** 43%
- **Median Age:**
  - **Male:** 58 years
  - **Female:** 60 years
- **Age Range:**
  - **Male:** 15–97 years
  - **Female:** 15–98 years

**Study Results**
- **Adverse Events:**
  - **Total:** 325 reported (12.1% of total patients).
  - **AEs:** 29% post-procedure pain, 29% other pain.

**Study Finding**
- The results of the study add to the existing body of evidence showing the safety of MSC treatments for orthopedic conditions.

**Study Conclusion**
- The study provides safety evidence for MSC treatments for orthopedic conditions.
- Further studies are needed to confirm these findings.

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**AE & SAE Reported**
- **Total:** 325 reported.
- **Percentage:** 12.1% of study population.
- **Groups:**
  - **SD:** 1.9%
  - **AD:** 1.5%
  - **CE:** 1.6%

**Table of AEs**

<table>
<thead>
<tr>
<th>AEs</th>
<th>Percentage</th>
<th>Study Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain Post Procedure</td>
<td>29%</td>
<td><strong>SD</strong> (stem cell injection only), <strong>AD</strong> (injection with adipose tissue), <strong>CE</strong> (injection with culture-expanded MSCs)</td>
</tr>
<tr>
<td>Other Pain</td>
<td>29%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Lab Work</td>
<td>5%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Immune</td>
<td>2%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Allergic</td>
<td>2%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Vascular</td>
<td>3%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Neurologic</td>
<td>5%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Cardiac</td>
<td>2%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Skin</td>
<td>2%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Infection</td>
<td>2%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Lab Work</td>
<td>5%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
<tr>
<td>Overall</td>
<td>10%</td>
<td><strong>SD</strong>, <strong>AD</strong>, <strong>CE</strong></td>
</tr>
</tbody>
</table>

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**Adverse Events by Month**
- **Month 1:** 12%
- **Month 2:** 3%
- **Month 3:** 2%

**Other Details:**
- The study was designed to be a safety study of MSC and MSC injections for the treatment of orthopedic conditions in a larger population.

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**Conclusion:**
The study provides safety evidence for MSC treatments for orthopedic conditions. Further studies are needed to confirm these findings and to explore longer follow-up periods.