

# Are Stem Cell Treatments Safe?

# This Study Sheds Light

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

## Study Facts



Resulted in the world's largest stem cell safety paper



The most comprehensive report of its kind



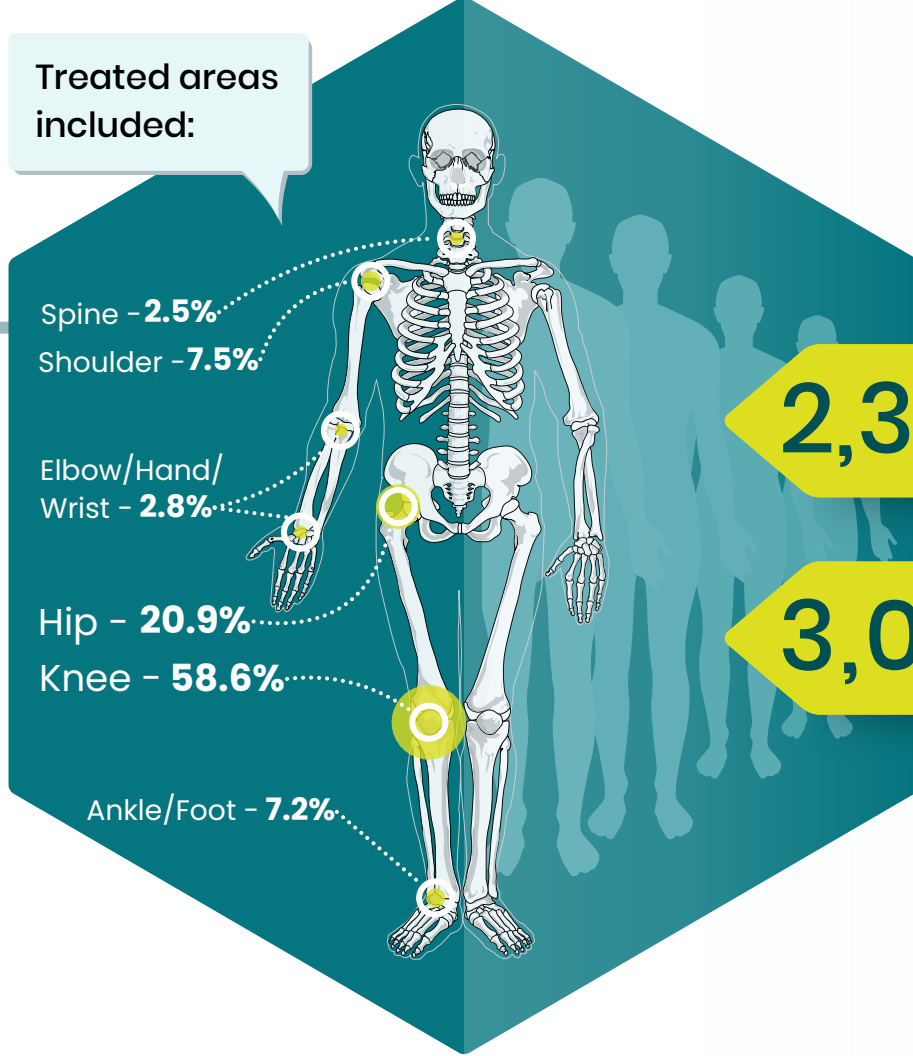
**2,372** SUBJECTS  
**9** YEARS

Followed the largest population for the longest time



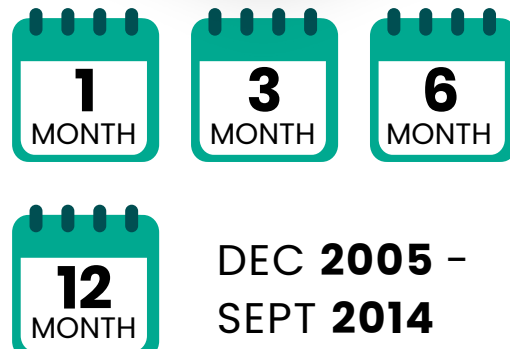
Analyzed the relative safety of several different treatment approaches

## Study Methods



## Study Subjects

Subjects were followed in a treatment registry at:



DEC 2005 - SEPT 2014

**2,372** Patients with orthopaedic conditions

**3,012** Mesenchymal stem cell (MSC) procedures

Median age of subjects:  
**57 YEARS**

Female population:  
**39.2%**

Male population:  
**60.8%**

### POST-TREATMENT REPORT

Registry data included subjects from **18** different clinical facilities



## Treatment Groups

SD Group:	AD Group:	CE Group:
<b>1,590</b>	<b>247</b>	<b>535</b>

Injection procedure with Bone Marrow Concentrate (BMC) only

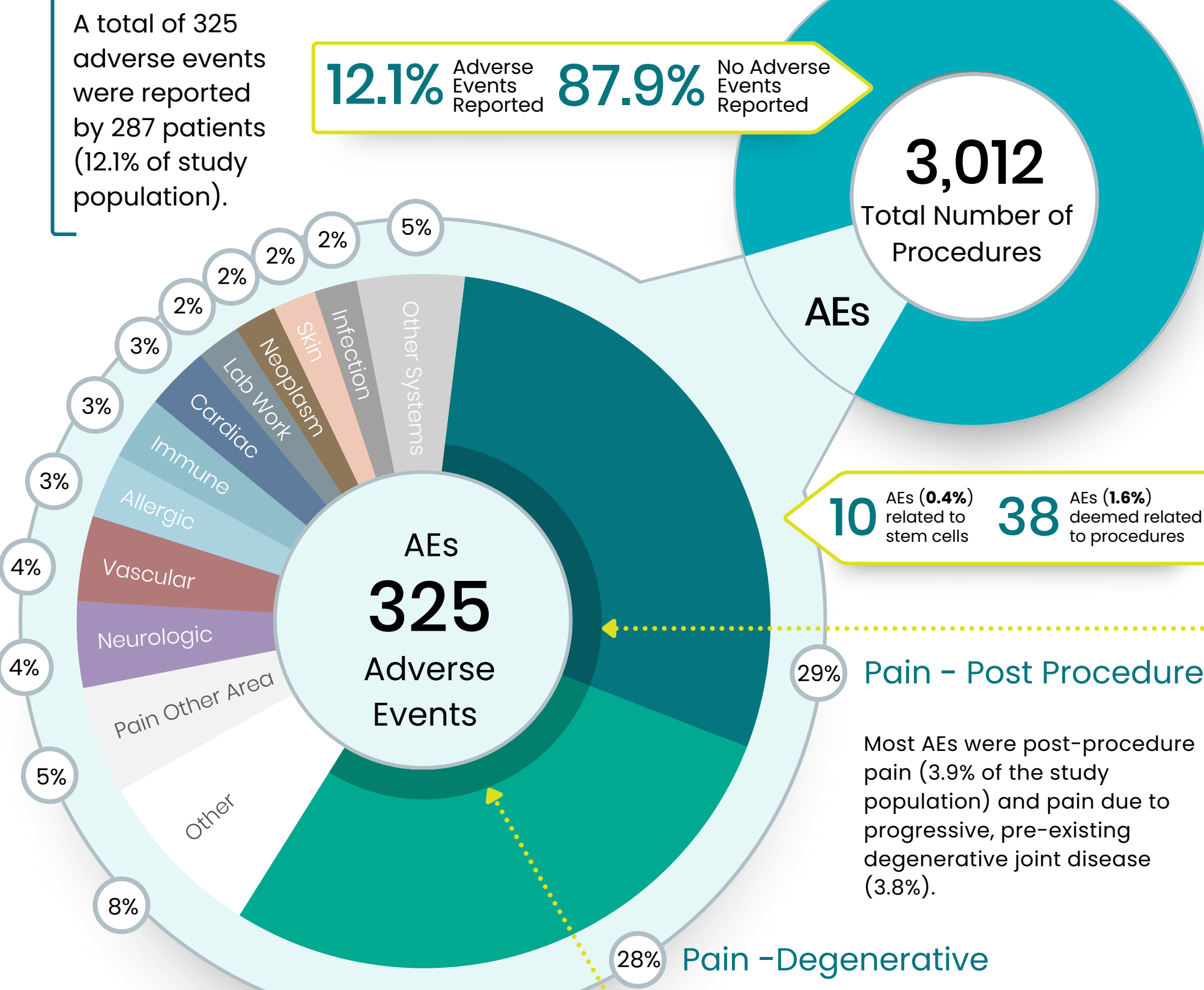
Injection procedure with BMC + adipose (fat) graft

Injection procedure with culture-expanded MSCs

## Study Results

Low rates of reported adverse events (AEs) among patients treated with mesenchymal stem cells (MSC) procedures, and substantially lower rates of serious or treatment-related AEs.

A total of 325 adverse events were reported by 287 patients (12.1% of study population).



### Any Adverse Events & Serious Adverse Events reported



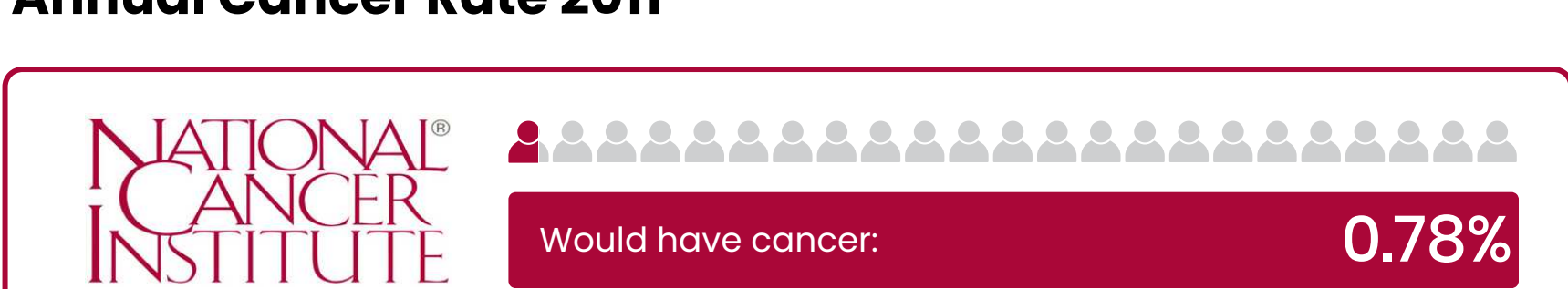
According to the **National Cancer Institute**, the **annual incidence of cancer** in the U.S. population in 2011 was **0.44%**, and **0.78%** in adults 50-64 years (~18.5 cases per 2,372 individuals).

In contrast, we observed a **lower annual cancer rate of 0.14%** (~3.3 / 2,372 patients) among our registry.

These findings are consistent with previous reports indicating no increased risk of tumor formations following BMC injections or treatments with culture-expanded MSCs (Mesenchymal stem cells).

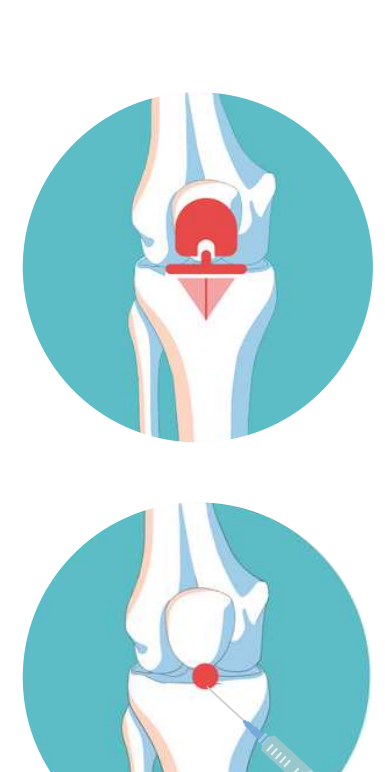
**No clinical evidence linking MSCs (mesenchymal stem cells) with an increased risk of cancer!**

### Annual Cancer Rate 2011



## Study Finding

Consistent with the safety profile of bone marrow concentrate (BMC) and mesenchymal stem cell (MSC) injections for the treatment of orthopaedic conditions in prior studies.



**260** PATIENTS who had total knee arthroplasty

**6%** SAE rates were at 3 months follow-up

Serious Adverse Event (SAE) rates were substantially lower than those reported for more extensive orthopaedic procedures (e.g., the SAE rate for total knee arthroplasty among 260 patients at three months follow-up was 6% [Kirschner]).

**2,372** Regenex<sup>®</sup> PATIENTS

**13** possibly related SAEs (0.55%) in the present study

**4** of these SAEs (0.17%) definitely related to the procedure

13 possibly related SAEs in the present study among 2,372 patients, approximately 0.55%, and only four of these SAEs (0.17%) were deemed definitely related to the procedure.

## Study Conclusion

The results of the study add to the existing body of evidence showing the safety of MSC-based therapies for orthopaedic conditions.

The full study can be read here:  
<https://pubmed.ncbi.nlm.nih.gov/27026621/>