



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.

Study Facts



Resulted in the world's largest stem cell safety paper



The most comprehensive report of its kind



Followed the largest population for the longest time

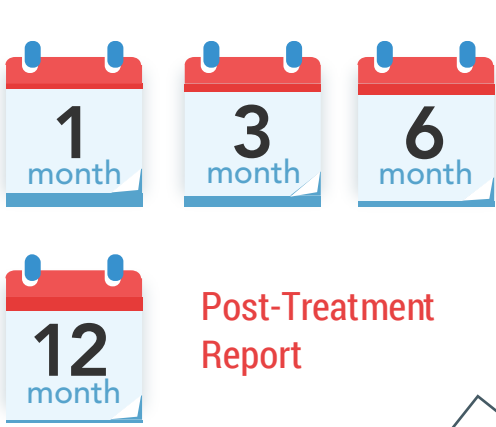


Analyzed the relative safety of several different treatment approaches

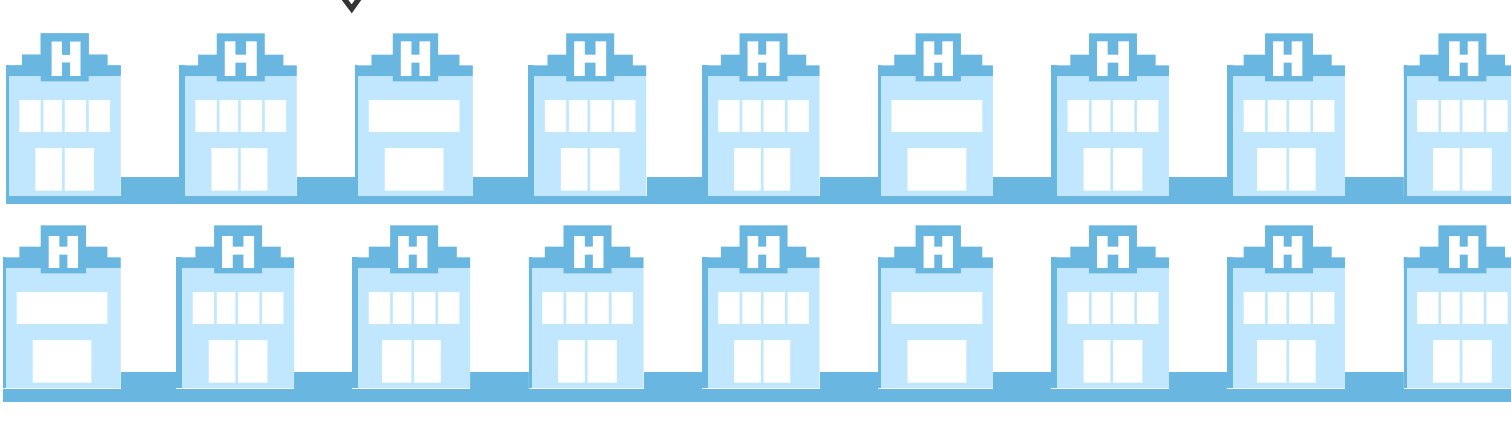
Study Methods

Subjects were followed in a treatment registry at:

Dec. 2005 – Sept. 2014



Registry data included subjects from 18 different clinical facilities



Treated areas included the:

- spine - 2.5%
- shoulder - 7.5%
- elbow/hand/wrist - 2.8%
- hip - 20.9%
- knee - 58.6%
- ankle/foot - 7.2%

Study Subjects

2,372 patients with orthopedic conditions

3,012 mesenchymal stem cell (MSC) procedures

Median age of subjects: **57 YEARS**

Female population: **39.2%**

Male population: **60.8%**

Treatment Groups

SD
Group:
1,590

Injection procedure with Bone Marrow Concentrate (BMC) only

AD
Group:
247

Injection procedure with BMC + adipose (fat) graft

CE
Group:
535

Injection procedure with culture-expanded MSCs

Study Results

Low rates of reported adverse events (AEs) among patients treated with 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).

12.1% Adverse Events Reported **87.9%** No Adverse Events Reported

3,012
Total Number of Procedures

AE's



10 AEs (0.4%) related to stem cells **38** AEs (1.6%) deemed related to procedures

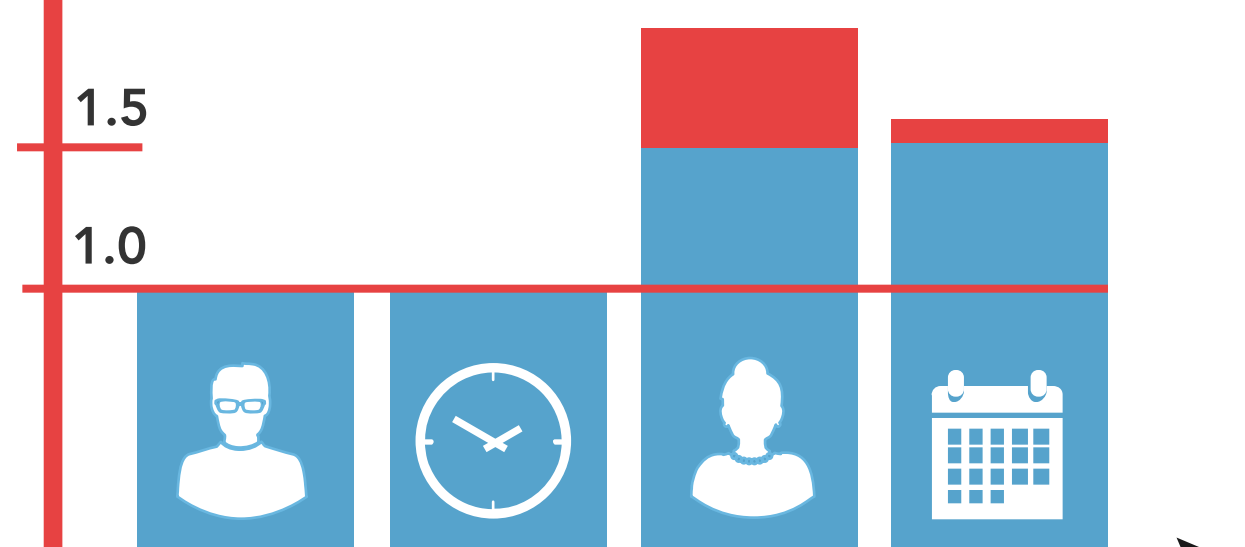
29% Pain-Post Procedure

Most AEs were post-procedure pain (3.9% of the study population) and pain due to progressive, pre-existing degenerative joint disease (3.8%).

28% Pain-Degenerative

Any AE & SAE reported

SAE reported (red bar)
AE reported (blue bar)



AEs and serious AEs were more common in older subjects, females, and those with longer follow-up periods.

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 0.14% (~3.3 / 2,372 patients) among our registry.

No clinical evidence linking MSCs with an increased risk of cancer!



2,372 PATIENTS

WOULD HAVE CANCER

Annual Cancer Rate **2011** **0.78%**

0.14%

HAVE REPORTED CANCER

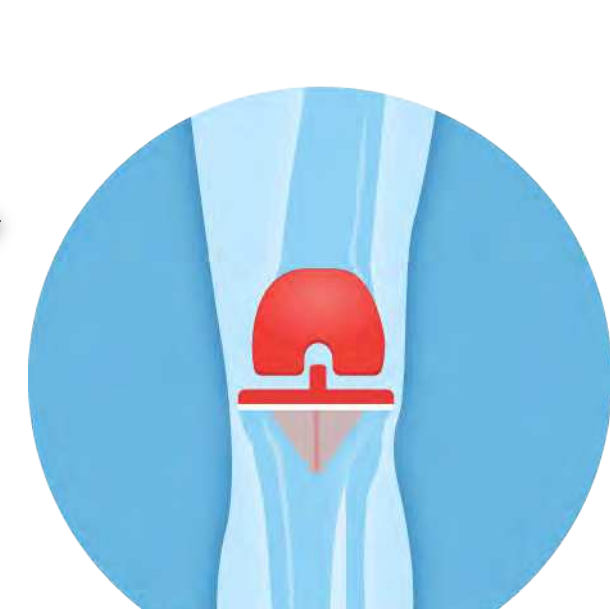
These findings are consistent with previous reports indicating no increased risk of tumor formation following BMC injections or treatment with culture-expanded MSCs.

Study Finding

Consistent with the safety profile of BMC and MSC injections for the treatment of orthopedic conditions in prior studies.

260 PATIENTS who had total knee arthroplasty

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

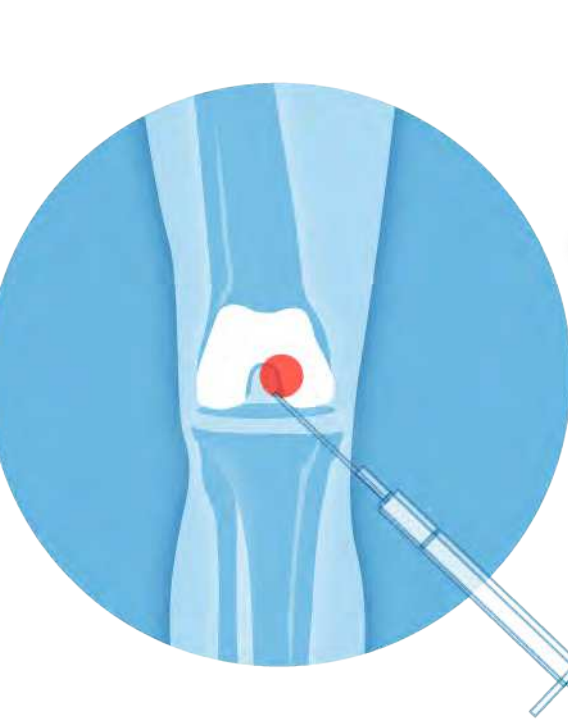


Serious AE (SAE) rates were substantially lower than those reported for more invasive orthopaedic surgical procedures (e.g., the SAE rate for total knee arthroplasty among 260 patients at three months follow-up was 6% [Kirschner]).

13 possibly related SAEs (0.55%) in the present study **4** of these SAEs (0.17%) definitely related to the procedure

2,372 PATIENTS

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 at this web address:

<http://link.springer.com/article/10.1007/s00264-016-3162-y>

