464

Kwon T G[1], Chun S Y[2], Choi J Y[1], Kim B S[1], Kim H T[1], Kim T[1], Yoo E S[1], Chung S K[1], Kim B W[1], Seo Y J[3], Lee K S[3], Shim K[4]

1. *Department of Urology, School of Medicine, Kyungpook National University,* ***2.*** *Joint institute for Regenerative Medicine, Kyungpook National University Hospital,* ***3.*** *Department of Urology, College of Medicine, Dongguk University,* ***4.*** *Departments of Urology, Andong Hospital, Andong, Korea*

PRE-CLINICAL EFFICACY AND SAFETY EVALUATION OF HUMAN AMNIOTIC FLUID-DERIVED STEM CELL INJECTION IN A MOUSE MODEL OF URINARY INCONTINENCE

Hypothesis / aims of study

Stem cell-based therapies represent new promise for treatment of urinary incontinence. This study was performed to assess optimized cell passage number, cell dosage, therapeutic efficacy, feasibility, toxicity and cell trafficking for the first-step of pre-clinical evaluation of human amniotic fluid stem cells (hAFSCs) therapy in a urinary incontinence animal model.

Study design, materials and methods

The proper cell passage number was analyzed with passage 4, 6, and 8 cells at week 2. The cell dose optimization was included with 1×10^4, 1×10^5 and 1×10^6 cells at week 2. The *in vivo* cell toxicity was performed with 0.25×10^6, 0.5×10^6 and 1×10^6 cells at week 2 and 4. Cell tracking was performed with 1×10^6 cells at week 2 and 4.

Results

The selected optimal cell passage number was less than 6 and the optimal cell dose was 1×10^6 for the mouse model. In our pre-clinical study, hAFSCs-injected animals showed normal values for several parameters; moreover, the injected cells were found to be non-toxic and non-tumorigenic. Furthermore, the injected hAFSCs were rarely identified by cell trafficking *in vivo* in the target organs at week 2.

Interpretation of results

hAFSCs-injected animals demonstrated normal values for parameters measured, and hAFSCs were found to be non-toxic and non-tumorigenic.

Concluding message

This study demonstrates for the first time the pre-clinical efficacy and safety of hAFSCs injection in the urinary incontinence animal model and provides a basis for future clinical applications.

References

1. De Coppi P, Bartsch G Jr, Siddiqui MM, Xu T, Santos CC, Perin L, et al. Isolation of amniotic stem cell lines with potential for therapy. Nat Biotechnol 2007;25:100-6
2. Kim BS, Chun SY, Lee JK, Lim HJ, Bae JS, Chung HY, et al. Human amniotic fluid stem cell injection therapy for urethral sphincter regeneration in an animal model. BMC Med 2012;10:94-107
3. Kim SO, Na HS, Kwon D, Joo SY, Kim HS, Ahn Y. Bone-marrow-derived mesenchymal stem cell transplantation enhances closing pressure and leak point pressure in a female urinary incontinence rat model. Urol Int 2010;86:110-6

Disclosures

Funding: grant of the Korea Healthcare technology R&D Project, Ministry for Health, Welfare & Family Affairs, Republic of Korea **Clinical Trial:** No **Subjects:** ANIMAL **Species:** Mouse **Ethics Committee:** Animal Ethics Committee of Biotoxtec Inc. and the Ethics Committee of Kyungpook National University School of Medicine