

Treating Ankylosing Spondylitis with SB Cells®

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ABSTRACT

Inflammanatory back pain is a common symptom in Ankylosing spondylitis patients [1]. Since there is no cure for the disease, current treatment focuses on lower the symptoms and preventing progression of the disease [2]. Many laboratories had tried to use stem cell to treat Ankylosing spondylitis related symptoms and receive positive response from patients. Here we used SB cells® to treat Ankylosing spondylitis patients. Not only patients showed lower pain symptom, but also patients did not report any side effect from the treatment. Here we used the SB cells® which purified from patients' own body in their stem cell treatment. With our initial success, we are planning to perform SB cells® treatment on a larger scale of Ankylosing spondylitis patients in the hope of obtaining larger data volume.

Abbreviation

SB Cells®: StemBios Stem Cells; AS: Ankylosing Spondylitis.

Introduction

In 2014, we published a paper for discovering one group of pluripotent stem cells from human bone marrow which we called SB cells® [1]. SB cells® are less than 6 um in diameter and express Lgr5 [1]. SB cells® can differentiate into endoderm-, mesoderm-, and ectoderm- cell types both in vitro and in vivo (done in mince) [1]. Since then, we expend our study and moved to testing SB cells®' regeneration ability in human. SB cells® have great promise in regenerative medicine and we hope to use SB cells® in diseases which currently have no cure such as Ankylosing Spondylitis (AS).

Ankylosing spondylitis is a type of inflammatory rheumatologic disease [2]. Patients with ankylosing spondylitis have inflammation from joints of their spine [3]. Patients tend to experience back pain and their affected joints tend to get stiff over time [3,4]. It is unclear what causes ankylosing spondylitis and there is currently no cure for this disease [3]. Development of the disease is generally known to be irreversible. Current treatment focuses on pain control, prevent progressive structural damage, and preserve motor function [5]. On the other hand, researchers have introduced stem cell treatment

in Ankylosing spondylitis and received positive results in many cases. In one study, patient with Ankylosing spondylitis who was treated with peripheral blood stem cell transplantation reported decreased posterior neck pain after 5 months post treatment [6]. Another study showed treating patients with allogenic intravenous infusion of bone marrow-derived mesenchymal stem cells was also shown to be effective [7].

Here at StemBios we had treated ankylosing spondylitis patients with SB cells® through IV infusion and we also received positive responses. Unlike most of the stem cell treatments which use a third party (donor)'s stem cell [6,7], we used SB cells® from patient him or herself. For our initial trial, we had three AS patients receiving SB cells® treatment. All three AS patients experience alleviated pain post treatment. There were no negative side effects reported in our first trial. With our initial success, we are proposing SB cells®-ankylosing spondylitis treatment in a large clinical skill to gather more data.

Methods

SB cells® were collected from patients using SB cells® purification protocol from our previous publication - Identification of a distinct small cell population from human bone marrow reveals

its multipotency in vivo and in vitro [1]. SB cells® were then injected back to patients following the guidelines described in our procedural IRB: SB-IN-4222.

Patients' health and pain symptoms were close monitored for 6 months post treatment. Patients were asked to complete questionnaire regarding their AS symptoms and positive/negative feeling post treatment up to 6 months post treatment.

Results

Based on patients' self-diagnoses, all of three AS patients experienced alleviated pain symptoms post treatment. Yet, the reduced pain effect varies amount patients. The alleviated pain lasted range from 3 months to 6 months. No negative side effect was reported during the 6 months post treatment period.

Conclusion

SB cells® treatment shows promising ability to manage patients' pain symptoms. Currently, there is no known side effect of SB Cells®. On the other hand, drugs used in treating AS result in many negative side effects such as headaches, abdominal bloating, nausea, oral ulcers, bone marrow suppression, increased risk of certain cancers [8]. Unlike other stem cell treatment methods, our treatment uses SB cells® which is obtained from patient him or herself which eliminate cross contamination when using stem cells from a third party donor. The purification method which we used to purify SB cells® is closed system which will lower the chances of sample contamination.

Next Phase Clinical Plan

With success of our current clinical data, we would like to extend the patient number and SB cells® treatment methods. We plan to have a total of 100 ankylosing spondylitis patients. The 100 patients will be divided into four groups, 25 patients per group. The first group will be control group which will receive IV infusion with saline only. The second group will be receiving one round of SB cells® treatment. The third group will be receiving two consecutive rounds of SB cells® treatment. The forth group will be receiving three consecutive rounds of SB cells® treatment. For

each round of the treatment, patients will have their blood sample collected on day 1 and SB cells® injected back to their body using IV infusion with 500mL saline bag on patients' arm on day 3. For each additional rounds of the treatment, patients will have their next blood sample collected 1 week after the previous blood collection and SB cells® will be injected on the third day after their blood collection. Patients' pain symptom will be closely monitored and followed up for 5 months.

Acknowledgment

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Consent

The risks, benefits, side effects, and alternatives have been discussed with the patient. The patient understands all post-procedure instructions and follow-ups. All questions were answered to satisfaction.

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