

Combination of statin-containing nanoparticles DDS and adipose derived stem cells studies on new therapeutic agents for scleroderma



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Scleroderma is a generic term for diseases in which the skin thickens, and there are roughly two types, localized scleroderma and systemic scleroderma (sclerosis). In the former, the disorder is stopped only in the skin, while the latter is regarded as a disease of unknown cause which causes severe symptoms such as fibrosis and vascular endothelial disorder over multiple organs in the body, and it is also designated for intractable diseases. (Designated intractable disease 51)

At present, each disease of each organ is dealt with by using steroid, cyclophosphamide, proton pump inhibitor, ACE inhibitor, endothelin receptor antagonist, etc. but it is said that there is no complete remedy.

In doing research to make it possible to cure the disease condition including this disease in general, by combining PLGA nanoparticle DDS containing simvastatin for anticholesterolemia treatment and mouse adipose-derived stem cells, it is possible to develop scleroderma. It was demonstrated by mice that excellent effects were obtained.

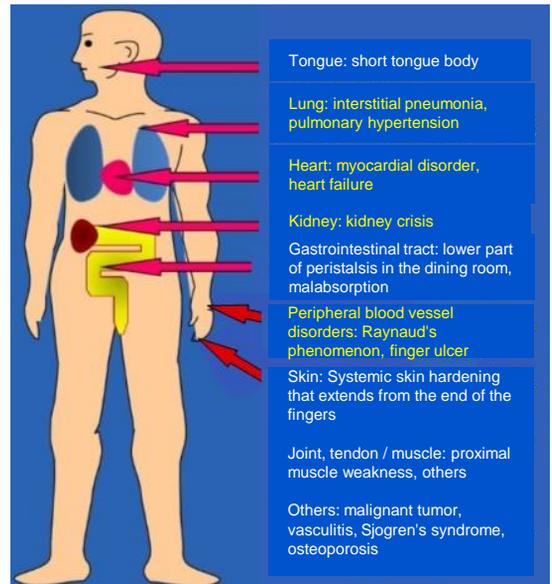
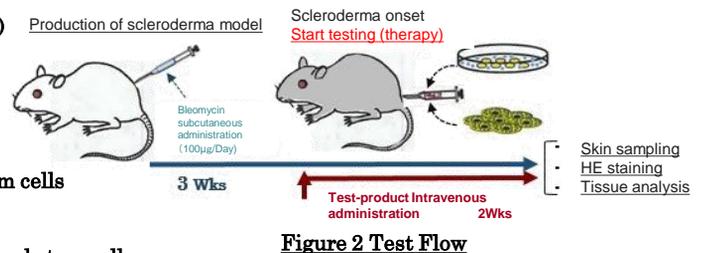


Fig. 1 Symptoms due to systemic scleroderma (website)

<Test Outline>

1. Preparation of scleroderma model mouse:
Bleomycin subcutaneous administration. (100 µg / day / 3 weeks)
2. Sample administration:
Sample intravenous administration for 2 weeks from 1 week after administration of bleomycin.
Administration 1: PBS (control),
Administration 2:
statin-free PLGA nanoparticle encapsulated adipose-derived stem cells (1 x 10⁴ Cell / mouse)
Administration 3:
Statin-containing PLGA nanoparticle encapsulated adipose-derived stem cells (1 x 10⁴ Cell / mouse)
3. 3 weeks after the start of examination Mouse dissection and skin tissue collection. Tissue section preparation, HE staining, histological analysis performed under a microscope.



<Result summary>

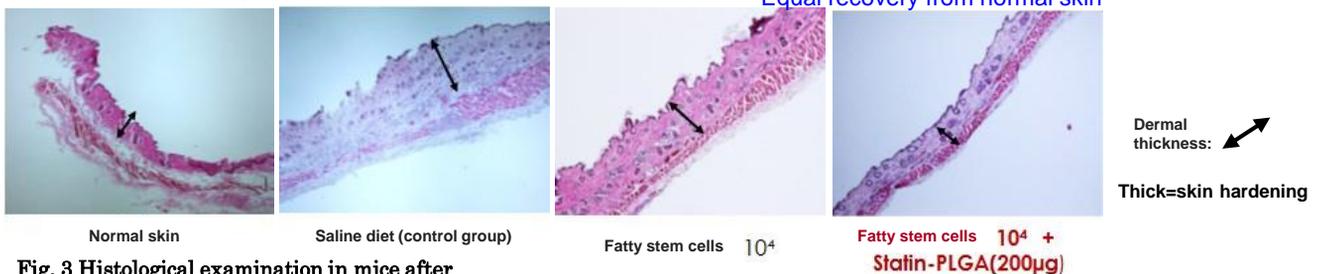


Fig. 3 Histological examination in mice after administration of each specimen

Dr.li et al. Made an international patent application on May 19, 2016 on this research (WO 2017191808 A1) and at the 17th BioTech research exhibition (held at the Tokyo International Exhibition Hall on June 28, 2018).

Based on this knowledge Novumcella signed a joint development research agreement with Osaka Medical University, and since the latter half of 2018, mainly at Osaka Medical University, preparations were made to conduct small-scale clinical trials on patients with specific scleroderma proceeding.

Furthermore, it is planned to proceed clinical trials and various related work to apply for approval in 2021.