

Study No. K920409

**Kanglaite Injection
Irritation Test in Quadriceps Femoris Muscles
of Rabbits**

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Summary

1 ml of KLT was injected into quadriceps femoris muscle of both sides in 3 rabbits. The injection sites were observed with naked eye and microscope after 24 hours of injection.

The results showed that the irritation reaction such as hyperaemia and hemorrhage was not observed in injection sites. The structures of muscle fibers and perimysium were normal with microscopic observation. There was no irritation reaction caused by KLT injected into quadriceps femoris muscles in rabbits.

1. Introduction

KLT is a white emulsion, which is being developed by Zhejiang Kanglaite Pharmaceutical Co., Ltd. according to traditional Chinese medicine theory. KLT was prepared by extracting the anticancer component from Chinese Herb Coicis Semen Yokuinin with modern technology.

The results of pharmacological study indicated that KLT showed significant antitumor effects against some animal transplantable tumors and human tumors xenograft.

KLT is expected to be useful in the treatment of human cancer.

2. Purpose

The purpose of this study was to observe the local irritation reaction of KLT injected into quadriceps femoris muscles of rabbits.

3. Test Materials

KLT, a white emulsion (Lot No 920605), was received from Traditional Chinese Medicine Hospital of Zhejiang Province on 20 June 1992.

4. Animals

Rabbits were purchased from Shanghai Navy Medicine Institute. The animals were given commercially available pellet diet and tap water ad libitum. The animal room environment was controlled at temperature of 22 to 26°C, relative humidity of 30-70% and a 12hr light/dark cycle. Animals were housed in suspended stainless steel cages individually. Body weight on the day of testing was 2.5-3kg.

5. Methods

1 ml of KLT was injected into quadriceps femoris muscle of both sides in 3 rabbits, and anatomized after 24 hours of injection, then observed with naked eye and microscope.

6. Results

6.1 Macroscopic Findings

The hyperaemia, hemorrhage, adhesive inflammation of irritation were not observed in the injection sites. The injection point could be seen cleanly on the surface of the quadriceps femoris muscles. The quality and color of the muscles were not any difference from the surrounding muscles. The muscles were anatomized along the injection site, the irritation such as hyperaemia and hemorrhage was not observed.

6.2 Micropathologic Findings

The structures of muscle fibers and perimysium were normal. The irritation such as vasodilation, hyperaemia and hemorrhage was not observed in the muscles.

7. Conclusion

Animal No.	Reaction of quadriceps femoris muscles					
	slight hyperaemia	middle hyperaemia	degeneration	necrosis	degree	
1	—	—	—	—	0	
2	—	—	—	—	0	
3	—	—	—	—	0	

The results showed that there was no irritation caused by KLT injected into quadriceps femoris muscles in rabbits.