Kanglaite Injection
Acute Toxicity Study in Mice with Administration
by the Intravenous and Intraperitoneal Routes

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Study Duration: 1992.7.10~1992.7.20

Quality Assurance Statement
This study conforms to the GLP recommendations issued by the State Science & Technology Commission of P.R. China. The report has been reviewed and authorized by the Department of Pharmacology of Shanghai Institute of Pharmaceutical (SIPI), State Drug Administration of China (SDA).

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Summary
This Toxicity Study was to determine the maximum-tolerated doses and principle toxicities of KLT in mice.

Forty mice (20 males and 20 females) were allocated to two groups. Twenty mice (10 males and 10 females) were used in each group. The mice received KLT ip or iv at dose level of 0.6ml/20g body weight once and 3 times within 24 hours. The total dosage was 90ml.kg⁻¹ day⁻¹ (1.8ml.20g⁻¹ .day⁻¹). The animals were observed for one week.

Results
1. There were no significant toxicity and death in mice with administration of KLT and during the observation period.
2. The maximum-tolerated dose of KLT administered ip or iv to mice was 90ml.kg⁻¹.day⁻¹.
3. The LD50 value of KLT administered ip or iv to mice was more than 90ml.kg⁻¹.day⁻¹

1. Purpose
This toxicity study was to determine the maximum-tolerated doses and principle toxicity of KLT in mice.

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

3. Animals
Kunming species mice were obtained from Shanghai Laboratory Animal Center. 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, relative humidity of 30-70% and a 12hr light/dark cycle. Animals were housed in groups of ten in suspended plastic cages. Body weight on the day of dosing was 19-21 g for males and females.

4. Methods
4.1 Dosages
Total dose was 90ml.kg⁻¹.day⁻¹(1.8ml.20g⁻¹ .day⁻¹) by intraperitoneal or intravenous routes respectively. This is the maximal dose of KLT administered to mice.

4.2 Groups and Administration
Forty mice (20 males and 20 females) were allocated to two groups. Twenty mice (10 males and 10 females) were used in each group. The mice received KLT ip or iv at dose level of 0.6ml/20g body weight once and 3 times within 24 hours. The animals were observed for one week. The mice were killed and necropsied at the end of the observation. The organs were macroscopically examined.
5. Results
Date of Dosing: 1992.7.10
Observation Duration: 1992.7.10-17
Necropsies: 1992.7.17

5.1 Deaths
No deaths occurred in either dosing route during the observation duration.

5.2 General Health Condition
Both the males and females mice showed slightly decreased locomotors activities after intravenous dosing immediately and recovered in 2-3 minutes.

There were no significant effects on general health condition in either males or females after intravenous or intraperitoneal dosing. All of the mice remained in good general health.

5.3 Body Weight
There were no significant effects on body weight gain in either males or females.

5.4 Food Consumption
There was no drug-related impairment of food. The mice consumed their feed normally.

5.5 Water Consumption
There were no effects on water consumption throughout the study duration.

5.6 Necropsy Findings
No abnormal pathological changes in all of the organs of the mice.

6. Conclusion
1. There were no significant toxicity and death in mice with intravenous or intraperitoneal administration of KLT.

2. The maximum-tolerated dose of KLT administrated intravenously or intraperitoneally to mice was 90ml.kg$^{-1}$.day$^{-1}$

3. The LD50 value of KLT administered intravenously or intraperitoneally to mice was more than 90ml.kg$^{-1}$.day$^{-1}$.