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

Author: Dr. Zhou Guoming
Shanghai Institute of Pharmaceutical Industry (SIPI)

Sponsor: Zhejiang Kanglaite Pharmaceutical Co., Ltd.

Shanghai Institute of Pharmaceutical industry (SIPI)

Personal Involved in This Study

Study Conductors: Zhou Guoming, Shen Jinli
Animal Service Manager: Yan Yonggao
Quality Assurance: Qian Beili

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).

Qian Beili, Professor
Chief QA
SIPI

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 19-21g 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}.