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EVALUATION OF ACUTE TOXICITY STUDY OF CIVAKARANTHAI ILAI CŪRANAM

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Abstract

The siddha medicine is among oldest system of medicine in India. The Civakaranthai ilai cūranam has been mentioned in classical literature Gunapadam Mooligai Vaguppu for the management of cegana vatham and it has been correlated symptoms in modern medicine in cervical spondylosis.

Objective: The objective of this study was to investigate the acute toxicity of siddha herbal formulation

Method: Acute toxicity of civakaranthai ilai cūranam (CKC) is carried out as per the OECD -423 guidelines on the acute toxicity study were used in female albino Wister rats. The test drug CKC was administered single dose at 5 mg/kg,50 mg/kg,300 mg/kg,1000 mg/kg,2000 mg/kg body weight of animal for 14 days administered all group of treated animals.

Results: The results are assessed for detect the effect of civakaranthai ilai cūramam .In acute toxicity study there is no mortality and behavioural changes are observed in treating the animals in civakaranthai ilai cūranam (2000mg/kg) indicating the p value is less than 0.05.

Conclusion: There were no mortality was observed in civakaranthai ilai cūranam (CKC).So civakaranthai ilai cūranam was safer and can be prescribed for therapeutic use in humans. **Keywords:** civakaranthai ilai cūranam, Siddha medicine, Toxicity study.

Introdution

One such valuable Siddha drug is Civakaranthai (Sphaeranthus amaranthoides Burn.f) from Siddha literature Gunapadam mooligai vaguppu has varied uses. The species being an annual stars growing in the post monsoon months of December & January, survives hardly for 5-6 months, and then is dried. (Sphaeranthus amaranthoides Burn. to family *Compositae* belongs the f(Asteraceae). It is an erect branced annual herb, the stem and branches glabrous, bearing simple, alternate, toothed decurrently leaves on the stem and branches. Root fibrous clustered developed enough to hold the plant in the marshy soil.

Leaves are simple, alternate, estipulate 2.5-7.5 cms long and varying width, linear oblong, obtuse serrulate slightly decurrent glabrous. Head inflorescence, each head with few or more outer flowers female fertile and few inner flowers bisexual corolla tubular fertile or sterile.

Materials and Methods Materials

2.1 Collection and authentication

The *Civakaranthai illai* collected from in and around areas of palayamkottai and thirunelveli, Tamilnadu and identified by the Medicinal botanist experts at Government Siddha Medical College and Hospital, Palayamkottai.

Purification and preparation

The adulterants from the raw drugs were removed, cleaned and dried in shades and grinded into chooranam.

Objectives

The aim of this Study is to evaluate the toxicity of the test substance CKC, when administered orally to Female Wister Rats with different doses, so as to provide a rational base for the evaluation of the toxicological risk to man and indicate potential target organs.

Guidelines Followed

(a) OECD Guidelines No. 423, The organization for Economic Co-operation and Development Panel of experts (OECD guidelines) defines acute toxicity as "the adverse effects occurring within a short time of administration of a single dose of a substance or multiple dose given within 24 hours (3)

Study Design and Controls

- 1) Female Wister Ratsin controlled age and body weight were selected.
- 2) The test drug CKC was administered at 5 mg/kg, 50 mg/kg, 300 mg/kg, 1000 mg/kg, and 2000 mg/kg body weight of animal as suspension along with water.
- 3) The results were recorded on day 0, with single oral dosing period of 14 days.

Experimental Procedure

Animals

A total of 15 Female Wister Rats with an approximate age of 6 weeks and purchased from CAP LABS Nagarkovil. The animals were used with approval of Institutional animal ethics committee (IAEC). The mean weights of Female Wister Rats were 100-150 g respectively. All animals underwent a period of 20 days of observation and acclimatization between the date of arrival and the start of treatment. All the rats had free access to a pelleted rat diet. The water was offered ad libitum in bottles. The test substance was administered orally. The Female Wister Rats belonging to the control group were treated with the vehicle (Water) at the same administration volume as the rest of the treatment groups.

Doses: The doses for the study were selected based on literature search and range finding study. Following the period of fasting, the animals were weighed and then drug was administered orally as single dose using a needle fitted onto a disposable syringe of approximate size at the following different doses.

Table: I Animal Dose Level

GROUP	DOSE
Group-I	5 mg/kg
Group-II	50 mg/kg
Group-III	300 mg/kg
Group-IV	1000 mg/kg
Group-V	2000 mg/kg

The test item was administered as single dose. After single dose administration period, all animals were observed for 14days.

Dose Preparation: CKC was added in distilled water and completely dissolved to form oral for administration. The dose was prepared of a required concentration before dosing by dissolving, in distilled water. It was mixed well. The preparation for different doses was vary in concentrations to allow a constant dosage volume.

Administration: The test item was administered orally to each Female Wister rats as single dose using a needle fitted onto a disposable syringe of appropriate size at the following different doses. The concentration of CKC was adjusted according to its body weight. The volume was not exceeding 10 ml/kg bodyweight. Variability in test volume was minimized by adjusting the concentration to ensure a constant volume at all dose levels.

Observation Period: All animals were observed for any abnormal clinical signs and behavioral changes. The appearance, change and disappearance of these clinical signs, if any, were recorded for approximately 1.0, 3.0 and 4.0 hours post-dose on day of dosing and once daily thereafter for14 days. **Mortality and Morbidity:** All animals were observed daily once for mortality and morbidity at approximately 1.0, 3.0 and 4.0 hours post dose on

day of dosing and twice daily (morning and afternoon) thereafter for 14 days

Results

Table No –II Physical and Behavioral Examinations

Group no.	Dose(mg/kg)	Observation sign	No. of animal affected.
Group-I	5mg/kg	Normal	0 of 3
Group- II	50mg/kg	Normal	0 of 3
Group-III	300mg/kg	Normal	0 of 3
Group-IV	1000mg/kg	Normal	0 of 3
Group-V	2000mg/kg	Normal	0 of 3

Statistical significance (p) calculated by one way ANOVA followed by Dennett's (n=6); ^{ns}p>0.05, *p<0.05, **p<0.01, ***p<0.001, calculated by comparing treated groups with control group

Data obtained in this study indicated $^{ns}p>0.05$ no significance physical and behavioral signs of any toxicity due to administration of *CKC* at the doses of 5mg/kg, 50mg/kg , 300mg/kg, 1000mg/kg and 2000mg/kg to rats.

Table No III Home Cage Activity

Functional and Behavioural observation	Observation	5mg/kg Group (G-I)	50mg/kg (G-II)	300mg/kg (G-III)	1000mg/kg (G-IV)	2000mg/kg (G-V)
		Female n=3	Female n=3	Female n=3	Female n=3	Female n=3
Body position	Normal	3	3	3	3	3
Respiration	Normal	3	3	3	3	3
Clonic involuntary Movement	Normal	3	3	3	3	3
Tonic involuntary Movement	Normal	3	3	3	3	3
Palpebral closure	Normal	3	3	3	3	3
Approach response	Normal	3	3	3	3	3
Touch response	Normal	3	3	3	3	3
Pinna reflex	Normal	3	3	3	3	3
Tail pinch response	Normal	3	3	3	3	3

Statistical significance (p) calculated by one way ANOVA followed by Dennett's (n=6); ^{ns}p >0.05, *p<0.05, **p<0.01, ***p<0.001, calculated by comparing treated groups with control group. Data obtained in this study indicated ^{ns}p >0.05 05 no significance changes in Home cage activity.

Functional and Behavioral observation	Observation	Control	5 mg/ kg (G-I)	50 mg/kg (G-II)	300mg/kg (G-III)	1000mg/kg (G-IV)	2000mg/kg (G-V)	
		Female n=3	Female n=3	Female n=3	Female n=3	Female n=3	Female n=3	
Reactivity	Normal	3	3	3	3	3	3	
Handling	Normal	3	3	3	3	3	3	
Palpebral closure	Normal	3	3	3	3	3	3	
Lacrimation	Normal	3	3	3	3	3	3	
Salivation	Normal	3	3	3	3	3	3	
Piloerection	Normal	3	3	3	3	3	3	
Pupillary reflex	Normal	3	3	3	3	3	3	
Abdominal tone	Normal	3	3	3	3	3	3	
Limb tone	Normal	3	3	3	3	3	3	

Table No IV: Hand Held Observation

Statistical significance (p) calculated by one way ANOVA followed by Dennett's (n=6); ^{ns}p>0.05, *p<0.05, **p<0.01, ***p<0.001, calculated by comparing treated groups with control group

Data obtained in this study indicated $^{ns}p>0.05$ no significance changes in hand held observation and signs of any toxicity due to administration of *CKC* at the doses of 5mg/kg, 50mg/kg, 300mg/kg, 1000mg/kg and 2000mg/kg to rats.

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Group no	Dose no(mg/kg)	Mortality
Group-I	5(mg/kg)	0 of 3
Group-II	50(mg/kg)	0 of 3
Group-III	300(mg/kg)	0 of 3
Group-IV	1000(mg/kg)	0 of 3
Group-V	2000(mg/kg)	0 of 3

Statistical significance (p) calculated by one way ANOVA followed by Dennett's (n=6); ^{ns}p>0.05, *p<0.05, *p<0.01, ***p<0.001, calculated by comparing treated groups with control group

From acute toxicity study it was observed $^{ns}p>0.05$ that the administration of *CKC*at a dose of 2000 mg/kg to the rats do not produce drug-related toxicity and mortality. So No-Observed-Adverse-Effect- Level (NOAEL) at *CKC* is 2000 mg/kg.

Discussion

The evaluation of acute toxicity in female wister albino rat was the highest overall concord of toxicity in animals. Scientific knowledge towards oral toxicity of siddha medicine is needed and it also helps identify the doses. In the acute toxicity of Siddha formulation CKC administrated at the dose of 2000 mg/kg by oral route and was observed for 14 days. The acute toxicity of civakaranthai ilai cūranam was carried out as per OECD-423 guidelines, no death was observed in both the animal groups which is control group and animals treated with maximum dose of 2000 mg/kg. Treated animals showed no evidence of toxicity. There is no evidence of behavioral performance, lacrimation. salivation. pupilaryreflex, abdominal and limb tone. There were no abnormalities in body position, touch and tail pinch response.

Conclusion

In conclusion no toxic effect was observed upto 2000mg/kg of *Civakaranthai ilai cūranam (CKC)* in Acute toxicity study. so, it can be concluded that the *Civakaranthai ilai cūranam (CKC)* can be prescribed for therapeutic use in human.

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