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Evaluation of Acute toxicity study of Siddha Drug *Eachuramooli Chooranam*

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Abstract

The Siddha system of medicine is one among the oldest systems of medicine in India. One of the important present day tasks is the necessity to prove to the world that Siddha system of medicine, which has been in existence since thousands of years, are not only safe but also scientific. One such valuable Siddha drug *is Eachuramooli (Aristalochia indica* Linn*)* from Siddha literature, "*Pathartha Guna Vilakkam*" [3] has varied uses, still there are no data on the safety profile of the drug *Eachuramooli chooranam (EC).* This study was undertaken to determine the acute toxicity of the drug *Eachuramooli chooranam (EC).*The acute oral toxicity test was performed following 423 guidelines of Organization for Economic Co-operation and Development (OECD) for testing of chemicals In Conclusion, no toxic effect was observed upto 2000mg/kg of *Eachuramooli chooranam (EC)* in Acute toxicity study.

Keywords: *Eachuramooli chooranam*, acute toxicity, Siddha, OECD 423 guidelines

1. Introduction

The Siddha system of medicine is one among the oldest systems of medicine in India. The term "Siddha" means achievement and "Siddhars" were saintly figures who achieved results in medicine through the practice of yoga. Siddha system's literature is in Tamil and it is practiced in the Tamil speaking parts of India [1]. One of the important present day tasks is the necessity to prove to the world that Siddha system of medicine, which has been in existence since thousands of years, are not only safe but also scientific.

Toxicity is defined as any harmful effect of chemical or a drug on a target organism. Acute toxicity has been defined by various experts. 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 [2].

Since ancient times innumerable complementary and alternative medicines especially in Siddha system of medicines possess with it a treasure effective treatments for various medical ailments. One such valuable Siddha drug *is Eachuramooli (Aristalochia indica Linn)* from Siddha literature, "*Pathartha Guna Vilakkam*" [3] has varied uses, still there are no data on the safety profile of the drug *Eachuramooli chooranam (EC). Aristalochia indica Linn* belonging to the family Aristalochiaceae is a perennial shrubby glabrous twiner with a long woody root stock; leaves simple, alternate, short petioled, entire with somewhat undulate margins; flowers greenish white or light purplish in axillary cymes or fascicles with swollen or inflated basal part, contracted middle part and narrow funnel shaped distal part; fruits rounded or oblong or hexagonal, septicidal 6 – valved capsules opening from below upwards; seeds flat, winged found growing throughout India at low elevations , on hedges and bushes[4].This study was undertaken to determine the acute toxicity of the drug *Eachuramooli chooranam (EC).*

2. Materials and Methods

2.1. Animals

Albino wistar rats weighing between 150-180 g were used for the study were obtained from the animal house of The Tamilnadu Veterinary and animal sciences university, Madhavaram milk colony, Chennai-600051and maintained in the animal house of National Institute of Siddha, Tambaram Sanatorium, Chennai, Tamil Nadu, India. Animals were housed in individually in polypropylene cages in a ventilated room (air cycles: 15/min; 70:30 exchange ratio) under an ambient temperature of 22±2°C and 40–65% relative humidity, with a 12-h light/dark artificial photoperiod. The animals received RO water ad libitum and fed with Rodent pellet. All the animals were acclimatized at least for 7 days to the laboratory conditions prior to experimentation. The study was conducted after obtaining prior approval (NIS/IAEC-V/09082017/03

2.2. Acute Toxicity Study-OECD 423 Guidelines

The acute oral toxicity test was performed following 423 guidelines of Organization for Economic Co-operation and Development (OECD) for testing of chemicals[5] . The animals were randomly grouped into two groups (n=3; female rats). Group I served as control group and group II served as drug treated group of which administered with *Eachuramooli Chooranam* at the fixed dose of 2000mg/kg.b.w by oral gavage. Drug treated group were keenly monitored for the emergence of the toxicity starting from time bound of 30 mins, 1h,2h,4h,8h,12h and upto 24 hours. Visual and behavioral signs with symptoms oriented to CNS, ANS, CVS and other respiratory functional toxicity including body weight and muscular coordination were observed for 14 days.

Observation includes the change in skin, fur, eyes and mucus membrane. Special attention was given to monitor the tremors, convulsions, respiratory distress, cardiovascular collapse, response to sensory stimuli, salivation, diarrhea, lethargy, sleep, coma and mortality. Observations were made and recorded systematically and continuously after study drug administration [6,7]. At the end of 14 days study period, all animals were subjected for gross necropsy and observed for pathological changes.

2.3. Statistical analysis

The statistical analysis was carried by one way analysis of variance ANOVA. Results are expressed as Mean ± SEM. The data were statistically analyzed by ONE WAY ANOVA followed by Dunnet's multiple comparison test. Probability P values <0.05 were considered as significant.

3. Results

3.1. Result Analysis of Acute Toxicity Study

3.1.1. Result Investigation of Acute Toxicity Profile of *Eachuramooli Chooranam*

As per the protocol directed by the organization for economic co-operation and development, the short term acute toxicity study of the test drug EC was carried out at the fixed dosage of 2000mg/kg.b.w. The test drug EC administered at the maximum of 2000 mg / kg b.w did not signify any adverse effects in the treated animals further there is no abnormalities were noted in any of the clinical signs. There is no mortality and morbidity were documented during the entire study period of EC treated animals.

Gross necropsy investigation did not reveal any abnormal pathology in any of the treated animal. No significant difference in body weight between control and test group. Similarly, there is no significant change in C.N.S, A.N.S and C.V.S related behavioral

activity in drug treated group. The results were tabulated **in Table 1**. Further, there is no significant change in sensory response of the drug treated group. No significant change was found in gross pathological observation of any of the vital of treatment group when comare to that of the control group animals. The results were tabulated **in Table 3.**

3.1.2.Effect of EC on Body weight of female rats in acute toxicity study

As per the OECD guidelines the acute toxicity study of *EC* was carried out at the dose level of 2000mg/kg.b.w. The test drug EC administered at the maximum of 2000 mg / kg b.w did not reveal any abnormal clinical signs in any of the animals. All the rats survived and no treatment related mortality occurred during the period of 14 days. Gross necropsy did not reveal any abnormal pathology in any of the animal. No significant difference in body weight gain was observed between control and test group. Weight loss was not observed in any of the groups treated with EC. Similarly, there is no significant change in C.N.S, A.N.S and C.V.S related behavioral activity in drug treated group. The results are tabulated in table 1.

Table 1: Effect of EC on Clinical signs of rats in Acute Toxicity Study

Clinical Signs	Group I	Group II
Lacrimation	Absent	Absent
Salivation	Absent	Absent
Animal appearance	Normal	Normal
Convulsion	Absent	Absent
Skin Color	Normal	Normal
Diarrhea	Absent	Absent
Touch Response	Normal	Normal
Mortality	Nil	Nil
Behavior	Normal	Normal

Values are mean ± SEM (n = 3), Statistical analysis carried out using One-way ANOVA followed by Dunnett's test

Further, there isno significant change in sensory response of the drug treated group. No significant change wasfound in gross pathological observation of any of the vital of treatment group when compare tothat of the control group animals. The results were tabulated in table 2 in which up to2000mg/kg there was no toxicity were observed, so the LD50 cut off is unclassified.

Table 2: Effect of EC on Body weight of female rats in Acute Toxicity Study

Treatment	Mean body weight in gms		
	1st Day	**7th Day**	**14th Day**
Group I - Control	165 ± 2.082	179.7 ± 7.688	188 ± 11.06
Group II – EC 2000 mg/kg	162.7 ± 4.055	170.7 ± 6.936	177.7 ± 8.988

Values are mean ± SEM (n = 3), Statistical analysis carried out using One-way ANOVA followed by Dunnett's test.

Table 3: Effect of EC on gross observation of vital organs of female rats in Acute Toxicity Study

Organ	Group I - Control	Group II – EC 2000 mg/kg
Brain	Normal	Normal
Lung	Normal	Normal
Heart	Normal	Normal
Liver	Normal	Normal
Stomach	Normal	Normal
Spleen	Normal	Normal
Kidney	Normal	Normal
Uterus	Normal	Normal
Ovary	Normal	Normal

4. Discussion

Traditional medicines are believed to be safer than chemical products. Therefore, toxicity studies of such formulations do not usually receive as much attention as studies of chemical products. However, some herbal based formulations are potentially toxic and may be harmful to human health. Therefore, scientific knowledge towards oral toxicity of siddha formulation is much needed, which will not only help identify doses that could be used subsequently, but also to reveal the possible clinical signs elicited by agents under investigation. In the acute toxicity study siddha formulation EC administered at the dose of 2000 mg/kg by oral route and was observed for 14 days. Results of the study shows that treatment with EC did not cause any death in rats. Treated animals showed no evidence of toxicity. Further there is no evidence of behavioral changes, neuro toxicity and cardiovascular toxicity was observed in this study. There were no abnormalities observed on the behavior performance, posture, gait and pupil change; no bizarre behaviors such as salivation and muscle trembling were observed.

Conclusion

In Conclusion, no toxic effect was observed upto2000mg/kg of *Eachuramooli chooranam (EC)* in Acute toxicity study. So, it can be concluded that the *Eachuramooli chooranam (EC)* can be prescribed for therapeutic use in human.

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Conflict of interest: Nil

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