

## Acute Toxicity Study Of Herbal Formulation of “Avaraivithathi Chooranam” In Albino Mice

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### ABSTRACT

**OBJECTIVE:** To evaluate the acute toxicity of herbal formulation of *Avaraivithathi chooranam* in albino mice.

**METHODS:** *Avaraiviththathi Chooranam* is administered by gastric intubations to the relevant group of animals orally at the dose of 50, 300, 2000 mg/kg body weight in Tween-80. The animals are then observed for 14 days and maintained with normal food. Toxic symptoms are observed for 72 hrs including behavioural changes, locomotion, convulsions and mortality.

**RESULTS:** There was no mortality or morbidity observed in animals through the 15-days period following single oral administration at all selected dose levels of the *Avaraiviththathi Chooranam*. The animals did not show any changes in the general appearance during the observation period. Gait and posture, reactivity to handling or sensory stimuli, grip strength was also normal.

**CONCLUSIONS:** No mortality was observed in both the animals of control group as well as animals treated with a maximum dose of 2000 mg/kg. These results indicate the safety of the oral administration of *Avaraivithathi Chooranam*.

## Key words

*AvaraivithathiChooranam*, Albino Mice, Acute -Toxicity, Dose

## INTRODUCTION

The herbal formulation of *Avaraivithathi chooranam* is very effective in treated Diabetes and their complications. Herbal drugs are alternative medicines for treatment of various diseases due to their assumed suitability, effectiveness, affordability, safety and low cost<sup>[1]</sup>. There is also an emerging increase in the consumption of herbal formulations by the public because of the strong belief that these products are natural; hence, they are safe for the treatment of ailments<sup>[2]</sup>. However, herbal preparations assumed to be safe may contain contaminants such as heavy metals<sup>[3]</sup>, aflatoxins and pathogenic microbes due to the manner in which they are prepared or as a result of acquisition of metals (e.g. cadmium) from the soil<sup>[4,5]</sup>. Determination of acute oral toxicity is usually the initial screening step in the assessment and evaluation of the toxic characteristics of all compounds. The types of toxicity tests which are routinely performed by pharmaceutical manufacturers in the investigation of a new drug involve acute, sub-acute and chronic toxicity. Acute toxicity is involved in estimation of LD50 (the dose which has proved to be lethal (causing death) to 50% of the tested group of animals).<sup>[6]</sup> The various dosage forms of *Avaraivithathichooranam* were analysed for their acute toxicity profile with reference to behavioural aspects in Albino mice. The limit test dose of 2000mg/kg body weight was used following OECD guidelines.<sup>[7]</sup>

## MATERIAL AND METHODS

The herbal formulation *Avaraivithathi Chooranam* was taken from the text book of *Sarabendra Vaidya Muraikal Neerizhivu Chikitsai*.

### Ingredients of *AvaraivithathiChooranam*

*Avaraivithathichooranam* contains Seeds of *Avarai* (Seeds of *Cassia auriculata*), Juice of *Atthippattai* (Bark juice of *Ficusrecomosa*), Juice of *Maruthampattai* (Bark juice of *Terminaliaarjuna*), Juice of *Nellippazham* (Fruit juice of *Phyllanthusemblica*), Juice of *Thanneervittankizhangu* (Tuber juice of *Asparagus recemosus*), Juice of *Vazhaikkizhangu* (Tuber juice of *Musa paradisiaca*), Juice of *Nerunjiver* (Root juice of

*Tribulusterestris*), Juice of *Seendhilkodi* (Juice of *Tinosporacordifolia*), Juice of *Sanbagapoo* (Flower juice of *Micheliachampaca*), Juice of *Kattrazhai* (Sap juice of *Aloe barbadensis*).<sup>[8]</sup>

### **Preparation of *AvaraivithathiChooranam***

*Avaraivithathichooranam* was prepared by the following method. The seeds of *Cassia auriculata* were soaked and dried each day in the 9 juices for each one day respectively. Then the seeds were dried in the shade until completely evaporated the moisture content. Then made into fine powder and kept in dried air tight container.<sup>[8]</sup>

### **Acute Toxicity Study**

The present study work was conducted in K.M. College of Pharmacy, Madurai - 625107. The herbal preparation *Avaraivithathichooranam* administered orally following acute oral toxicity of *AvaraiviththathiChooranam* is carried out as per the guidelines Organization of Economic Co-operation and Development (OECD) -423 guidelines after the animal ethical clearance from Institutional Animal Ethics Committee. The experiment was approved by the institutional ethical committee (IAEC) under CPCSEA (approval no:TNMGRMU/KMCP/IEAC/316)

The Swiss albino mice are fasted overnight and provided only water, after which the *AvaraiviththathiChooranam* is administered by gastric intubations to the relevant group of animals orally at the dose of 50 mg/kg body weight in Tween-80. The animals are then observed for 14 days and maintained with normal food. A mortality rate of 2 or 3 animals in 14 days is recorded and the dose is said to be toxic dose. But when mortality of one animal is observed, then the same dose is repeated again for confirmation. However, if mortality is not observed, the procedure is repeated for further higher doses such as 300 and 2,000 mg/kg body weight. Toxic symptoms are observed for 72 hrs including behavioural changes, locomotion, convulsions and mortality<sup>[9, 10]</sup>.

### **CAGE SIDE OBSERVATIONS**

Observations include changes in skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous systems, and somatomotor activity

and behaviour pattern. Special attention is directed for the observation of tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma. Body weight, food and water intake are recorded at two-day intervals. Surviving animals are fasted overnight, weighed and humanely killed on the 15th day using anaesthetic ether. All test animals are subjected to gross necropsy.

## RESULTS AND DISCUSSION

All the animals were carefully observed for development of any toxic signs or symptoms at different time intervals of 0, 30 minutes, 1, 2, 4, 6, 8, 12 hrs and then daily for period of 14 days. No abnormal sign of symptoms were observed in any of the animal fed with *Avaraiviththathi Chooranam*. There was no mortality or morbidity observed in animals through the 15-days period following single oral administration at all selected dose levels of the *Avaraiviththathi Chooranam* (Table-1). The animals did not show any changes in the general appearance during the observation period. Morphological characteristics such as fur, skin, eyes and nose appeared normal. No tremors, convulsion, salivation, diarrhea, lethargy or unusual behaviors such as self-mutilation, walking backward and so forth were observed. Gait and posture, reactivity to handling or sensory stimuli, grip strength was also normal. No mortality was observed in any animal indicating its safety. Clinical examinations of all the rats were normal and necropsy findings did not show any remarkable findings.

	Dose (mg/kg)	Sign of Toxicity (ST.NB <sup>-1</sup> )	Mortality (D.S <sup>-1</sup> )
<b>Group I</b>	0	0/3	0/3
<b>Group II</b>	300	0/3	0/3
<b>Group III</b>	2000	0/3	3/3

**In Table.1**, acute toxicity study of *Avaraiviththathi Chooranam* on experimental albino mice. The acute toxicity of *Avaraiviththathi Chooranam* on experimental mice was tested using OECD-423 guidelines, where ST- sign of toxicity; NB- normal behavior; D- died; S- survive. Values are expressed as number of animals (n=3).

## CONCLUSION

Hence, from the present study it can be concluded that the medicine *Avaraiviththathi Chooranam* is nontoxic at the limit dose of up to 2000 mg/kg body weight. Therefore, it can be recommended as a safe product to replace synthetic medicines and for regular usage. Further studies are warranted for determining chronic toxic symptoms.

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