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ORIGINAL RESEARCH ARTICLE

Acute Toxicity Study of Parangipattai Rasayanam (PRM) in Mice: A Safety Assessment (WHO guidelines, 1993)

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ABSTRACT

The Present Study was planned to assess the acute toxicity of PRM. Swiss albino mice were orally administratedsingle dose of 180mg/kg drug was mix with milk. Mortality, signs of toxicity, bodyweight, food consumption and gross findings were observed for 14 days post treatment of *PRM*. Inaddition, no significant differences were noticed in the body and organ weights between the control and treated groups.These results state that PRM is toxicologically safe by oral administration.

Key words: Parangipattai Rasayanam [PRM], Acute toxicity, PHF.

1. INTRODUCTION

This polyherbal formulation (PHF) is traditionally used in various diseases like psoriasis, ringworm and itching.The PHF contains several medicinal herbal plants like Parangipattai (*Smilax china*, Linn), Kodiveli (*Plumbago indica*, Linn), Amukkara (*Withania somnifera*, Linn). In the past, a number of studies have been carried out on these plants for testing their pharmacological activities [1-5]. Though some isolated toxicity studies are reported of individual agents [6].The purpose of the present study is to investigate acute oral toxicity of PRMin mice

2. MATERIALS AND METHODS

a. Principle

Acute toxicity was carried out in Swiss albino mice with a single exposure of 10 times of the recommended therapeutic dose of test compound (**Table 1**). The study duration was 14 days.

Animal species : Swiss albino mice
Age / Weight / Size : 6 weeks; Mice: 20-25gms.
Gender : Both male and female
Number of Animals : 20 Mice
Acclimatization Period : 07 Days

Table 1: Animal dosage

S. No	Group	No of mice
1	Vehicle control	10 (5 male, 5 female)
2	Toxic dose 10xTherapeutic dose (180mg)	10 (5 male, 5 female)

b. Test animals

Test animals were obtained from the animal laboratory of the King Institute, Chennai [7] and stocked at Animal house, National institute of Siddha, Chennai. All the animals were kept under standard environmental condition (27± 2º C).The animals had free access to water and standard pellet diet (Sai Meera foods Pvt. Ltd, Bangalore) [8].The principles of laboratory animal care were followed and the Institutional ethical committee approved the use of animals and the study design (1248/ac/09/CPCSEA/4-08/2011 - 20/12/2011).

c. Route of administration

Oral route was selected, because it is the normal route of clinical administration.

d. Test substance and vehicle

The Parangipattai Rasayanam is brownish color. The test substance was insoluble in water. In order to the test, the drug was mix with milk

e. Administration of doses

Parangipattai rasayanam was Mix with milk, with uniform mixing and it was administered to the groups in a single oral dose. The control groups received equal volume of the vehicle. The animals were weighed before giving the drug. The dose level was calculated according to body weight, and surface area. It was converted to animal dose

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(180mg) and then administered. The principle of laboratory animal care was followed.

f. Observations

Observations were made and recorded systematically and continuously observed as per the guideline after substance administration. Animals were observed individually. Visual observations included skin changes, alertness, grooming, aggressiveness, sensitivity to sound, touch and pain, restlessness, tremors, convulsion, righting reflex, gripping reflex, pinna reflex, corneal reflex, writhing reflex, papillary reflex, urination, salivation, lacrimation for first 4 hrs, then periodically during the first 24 hrs. Animals were observed for body weight and mortality for 14 days. If animals dye during the period of study, the animals were sacrificed. At the end of the 14th day all animals were sacrificed and microscopy was done.

d drug treated group

3. RESULTS AND DISCUSSION

Parangipattai Rasayanam at the dose 180mg/animal did not exhibit any mortality in mice.No behavior changes were noted for the first 4 hours and for the next 24 hours and throughout the study period of 14 days. There was no significant weight reduction was noted before and after the acute toxicity study duration (**Fig 1**). Reflexes were found to be normal in any of the drug treated or control animals. All the animals appeared alert and in good health. There was no mortality in any of the drug treated or control animals during the 14 days period of study. In Necropsy, the organs of the animal such as Liver, Heart, Lungs, Pancreas, Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.

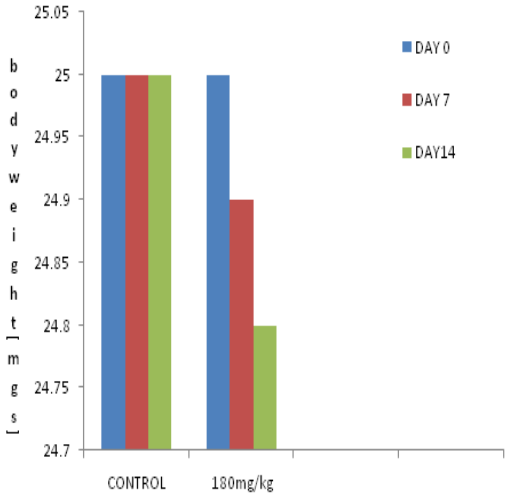

Figure 1: Animal body weight is compared to control group and drug treated group.

In conclusion, it can be said, that acute toxicity studies in mice did not show any significant toxic effect and thus substantiate the claim of safety of the drug.

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