

Acute Toxicity Study of Malli Chooranam a Siddha Formulation

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Abstract:- Chooranam is a powdered form of herbal drugs and filtered by using the fine cloth which is called as Vasthirakaayam. Mallichooranam (MC) is one among them used to remove kabha diseases. This chooranam contains 10 ingredients all have phytochemicals which cure diseases. This formulation is indicated for *Thondaipun, Thondaikammal, etc.* in the Siddha Classical text book *Shikicha RatnaDeepam*. Preclinical and safety monitoring was essential for standardization and global acceptance of this drug. For acute toxicity study, Swiss Albino Mice was used and it was exposed to ten times the suggested therapeutic dose of test compound once and the period of the study will be fourteen days as per OECD guideline 423. Totally 20 animals were used, each group contain 10 animals which include 5 male and 5 female. MC was suspended in aqueous Tween 80 solution (30%), with uniform mixing and it was provided to the test groups in a single dose through oral route. It was observed that MC at the dosage of 54mg/animal does not cause any death in the study subjects. Behavioural changes were not known for the first 4 hours and for the next 24 hours and for entire duration of study of 14 days. In course of the study, weight of test groups were not diminished. In the initial time and after the completion of the study reflexes were found to be normal as well as all other observations were found to be normal. In Necropsy, the internal organs of respiratory system, digestive system, reproductive system of the test groups all appeared normal.

Keywords:- Malli Chooranam, Siddha Formulation, Acute Toxicity Study, Kabha Diseases.

I. INTRODUCTION

In Siddha system two varieties of medicine are used. One is internal and another is external medicine. In internal medicine they are classified into 32 varieties one among them is chooranam. It is a powdered form and filtered by using fine clothes (Vasthirakaayam)^[1].

Malli chooranam is the powdered form of medicine. It contains *Kothamalli*-*Coriandrum sativum*(Linn), *Ilavangapattai* -*Coriandrum sativum*(Linn), *Ilavangam*-*Syzygiumaromatica* (Linn) Merrill & Perry, *Elam* -*Elettaria*

cardamomum(Linn), *Karunseeragam* -*Nigella sativa*(Linn), *Thiraatsai* -*Vitis vinifera* (Linn), *Athimaturam* - *Glycyrrhiza glabra* (Linn), *Seeragam* - *Cuminum cyminum* (Linn), *SeemaiSeeragam* - *Carum bulbocastum*(Koch), *Parangipattai*- *Smilax china*(Linn). All the ingredients helps to remove Kabam (Phlegm). This formulation is indicated for *Thondaikammal, Thondaipun, , Kaatthadaippu, Vikkal, Vaanthi Arosikam, Athikaviyarvaividuthal, Kaikaalerichal* in the Siddha classical text book *ShikichaRatnaDeepam*^[2]. Mallichooranam formulation was practised by Siddha physician year long ago. This drug was clinically effective in kabha diseases also in paediatric cases.

For the standardization and global acceptance of this drug needs some preclinical and safety monitoring, so the author decides to assess the Acute toxicity of the polyherbal formulation Mallichooranam before conducting clinical studies.

II. MATERIALS AND METHODS

Preparation of the Drug:

The raw drugs were purchased in the local market and it was certified by Botanist in National Institute of Siddha, Tambaram Sanatorium, Chennai.

The raw drugs were purified as per the Siddha literature ^[3]. Each purified raw drugs were powdered separately to fine powder and mixed evenly. Then filtered by using cloth (Vasthirakayam)^[4]. Finally chooranam was used to assess the safety and clinical study.

Principle:

An acute toxicity study was carried out in Swiss albino mice which was subjected to single exposure of 10 times of the suggested therapeutic dose of test compound and the study period will be 14 days^[5].

Animal species: Swiss albino mice

Gender : Both male and female

Age / Weight / Size : 6 weeks. Mice-20-25 gms.

Number of Animals : Mice: 10

Acclimatization Period : 7 Days

Clinical dose : 5.0 gms \day

Table No: 1 Grouping of Animals

S. No	Group	No of mice
1	Vehicle control (saline)	10 (5 male, 5 female)
2	Toxic dose (10X therapeutic dose) (54mg)	10 (5 male, 5 female)

Test Animals:

Test animals Swiss albino mice were obtained from the animal laboratory of the King institute, Chennai and stocked in animal house at National institute of Siddha, Chennai. In the animal house they were maintained under standard environmental condition (27⁺ or 2[°]C). The test groups had free admittance to water and standard pellet diet. The laboratory animal care principles were maintained. To utilize animals and for the study design got approval from the Institutional ethical committee. (1248/ac/09/CPCSEA/February/ 2012)

Route of administration:

Normal route of clinical administration that is Oral route was selected. The test substance MC is insoluble in water, in order to achieve and ensure the uniformity in drug distribution the drug is dissolved by aqueous Tween 80 solution (30%). Malli Chooranam was suspended in aqueous Tween 80 solution (30%), with uniform mixing and it was administered to the test animals in a single oral dose.

Equal volume of the vehicle were given to control groups. Before giving the drug the animals were weighed. According to body weight, and surface area, the dose level of drug was calculated. The clinical dose was 3.0gms/day and it was changed to animal dose (54mg) and then given orally.

Observations:

Observations were made and recorded systematically and continuously observed as per the guideline after substance administration.

The animals were monitored for behavioural parameters like

1. Awareness
 - Alertness
 - Stereotype
 - Passivity
 - Visual placing
2. Mood
 - Fearfulness
 - Restlessness
 - Irritability
 - Grooming
3. Motor activity
 - Pain response
 - Touch response
 - Spontaneous activity
 - Reactivity

In this 14 days of study period animals were perceived for body weight and mortality. During this period of study, if animals were died they were considered to be sacrificed. At the end of the 14th day all animals were sacrificed and necropsy was done. Animals were weighed individually before and after the test compound was administered and daily for 14 days. Any change in weight were observed and noted. Finally, surviving animals were weighed and sacrificed for observing purpose.

III. RESULTS

MalliChooranam at the dose 54mg/animal did not cause any mortality in animal species(mice). No behaviour changes were noted for the first 4 hours and for the next 24 hours and throughout the study time of 14 days. Reduction in weight was not noted before and after the acute study period. Reflexes were found to be normal and all other observations were found to be normal initially and finally in the study time. In Necropsy, the internal organs of respiratory system, digestive system, reproductive system of animals all appeared normal.

IV. CONCLUSION

In the present work, the acute toxicity of Malli choornam by oral administration in Swiss albino mice were performed. The result suggests that the administration of test substance with no signs of toxicity and it was safe. This study was considered as a preclinical step for further clinical study.

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