Acute toxicity study of polyherbal formulation-Ilavangathi Choornam

S. Bhavani

Siddha Central Research Institute, Arumbakkam, Chennai

ABSTRACT

The current study was designed to study acute oral toxicity study of Polyherbal formulation Ilavangath ichoornam according to OECD guidelines. Three albino rats were used for the study. Ilavangath ichoornam in five single oral doses was supplemented to all rats. The parameters like general appearance, behaviour, bodyweight, mortality, and necropsy were studied. No change in general appearance and mortality was observed. Ilavangath ichoornam was found to be safe at dose of 2000mg/kg.

Keywords: Polyherbal formulation, albino rat, acute oral toxicity, LD50

INTRODUCTION

The Polyherbal drug, Ilavangath ichoornam is mentioned in Siddha literature(1) which is indicated for wheezing, fever, cough, abnormal uterine bleeding, peripheral neuritis, haemorrhoids, diarrhoea, giddiness etc.

This trial drug consists of twenty nine raw drugs namely, Cinnamomum zeylanicum, Cinnamomum verum, Anethum graveolens, Nigella sativa, Elatteria cardamom, Coriander sativum, Cuminum cyminum, Abies spectabilis, Clerodendron serratum, root of Piper longum, Piper nigrum, Nardostachys jatamansi, Myristica fragrans, Maze of Myristica fragrans, Trachyspermum ammi, Costus speciosus, Hyocamus niger, Embelia ribes, Quercus infectoria, Anacyclus pyrethrum, Barringtonia acutangula, Mesua ferrea, Alpinia officinalis, Zingiber officinale, Piper nigrum, Piper longum, Sida acuta, Plectanthres amboticus, Trigonella foenum graecum.

EXPERIMENTAL SECTION

ACUTE TOXICITY STUDIES:

In order to assess the safety of a drug various toxicity studies are carried out in animals under varying conditions of drug administration. The LD50 is determined trial drug using albino rats. Doses of the compound are given to 5 groups of albino rats each in a geometrical progression starting with a dose of 175 mg / kg and mortality in 24 hrs recorded.

PROCEDURE:

ACUTE ORAL TOXICITY (24 hrs observation) up and down procedure (OECD 425)
1. Animals - Albino rats (recommended species)
2. Sex - Female (non pregnant)
3. Group - Five groups
4. Total number of animals used – 15
5. Dose levels used:
175 mg / kg  
520 mg / kg  
1000 mg / kg  
2000 mg / kg  
5000 mg / kg

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Dose level</th>
<th>No. of animals exposed</th>
<th>No. of animals showing toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>175 mg / kg</td>
<td>3</td>
<td>Nil</td>
</tr>
<tr>
<td>2.</td>
<td>520 mg / kg</td>
<td>3</td>
<td>Nil</td>
</tr>
<tr>
<td>3.</td>
<td>1000 mg / kg</td>
<td>3</td>
<td>Nil</td>
</tr>
<tr>
<td>4.</td>
<td>2000 mg / kg</td>
<td>3</td>
<td>Nil</td>
</tr>
<tr>
<td>5.</td>
<td>5000 mg / kg</td>
<td>3</td>
<td>2 (hyperactive)</td>
</tr>
</tbody>
</table>

7. Body weight - 175 - 250 g
8. Time of dosing - 9.30 am on 8.03.2007  
Time of toxic effect after dosing- 7.45 am on 9.03.2007
9. No macroscopical changes observed in all groups
10. Toxic effects - 175 mg / kg - Normal  
After 4 hours 520 mg / kg - Normal with increased movement  
After 4 hours 1000 mg / kg - Active, grooming behaviour  
After 3 hours 200 mg / kg - Active, somersault acting, rearing action  
5000 mg / kg - Hyperactive, aggressive increased fighting behaviour  
After 6 hrs of dosing - moribund animals
11. Caging conditions:  
Animals are housed in polypropylene cages of 3 animals / cage  
i). bedding material : Rice Husk  
ii). Temperature : 22 – 25°C  
iii). Humidity : 50%  
iv). Photoperiod : 12 hr light, 12 hr dark cycle  
v). Diet : Standard pellet diet  
(Hindustan lever & co / Bangalore)  
Water ad libitum
12. Vehicle used for suspending test substance: corn oil
13. Route: Oral
14. Observation period: 24 hrs

RESULTS

After observation over 24 hrs, 2000 mg / kg is the LD_{50} and the dose fixed is 1/10 of LD_{50} is 200 mg / kg.

DISCUSSION

The polyherbal formulation Ilavangath ichoornam is used in the treatment of Cough, Wheezing, peripheral neuritis, giddiness, diarrhoea, menorrhagia, haemorrhoids, fever etc. The present study was conducted to evaluate the safety of the drug, as it contains numerous mixture of herbal raw drug as constituents. However, each of these herbal may contain different active constituents that are responsible for its medicinal and toxic effects. This makes mandatory to evaluate the toxic effect of this polyherbal formulation at different doses. In the present study, this compound drug was found to be safe up to 2000mg/kg orally.

The present study confirms that this polyherbal formulation is practically non-toxic & safe. In the present study, other organs too, did not show any significant changes.

CONCLUSION

The results of the present study conclude that Ilavangath ichoornam is safe or practically non-toxic when administered orally. This is only a preliminary study, in the future this research will pave an opportunity to conduct clinical trials in human subjects.

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REFERENCES