wjpmr, 2018,4(11), 132-134

SJIF Impact Factor: 4.639

WORLD JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.wjpmr.com

Research Article

ISSN 2455-3301

WJPMR

ACUTE DERMAL TOXICITY STUDY OF A SIDDHA POLYHERBAL FORMULATION KARAPPAN ENNAI IN RATS

Dr. Rajeshwari E.*[1], Gandhimathi S.[2], Meenakumari R.[3] and Muralidharan P.[4]

[1]PG Scholar, Department of Kuzhanthai Maruthuvam, Government Siddha medical College, Chennai 106, Tamilnadu, India.

[2]Lecturer, Department of Kuzhanthai Maruthuvam, Government Siddha medical College, Chennai 106, Tamilnadu, India.

[3]Professor and HOD, Department of Kuzhanthai Maruthuvam, Government Siddha medical College, Chennai 106, Tamilnadu, India.

[4]Professor and Head of the Department of Pharmacology and Toxicology, C.L.Baid Metha College of Pharmacy, Chennai 97, Tamilnadu, India.

***Corresponding Author: Dr. Rajeshwari E.**

PG Scholar, Department of Kuzhanthai Maruthuvam, Government Siddha medical College, Chennai 106, Tamilnadu, India.

Article Received on 27/08/2018 **Article Revised on 17/09/2018** **Article Accepted on 08/10/2018**

ABSTRACT

Karappan ennai,[1] a compound of Siddha polyherbal formulation is indicated for skin diseases particularly Karappan[2] (Atopic dermatitis) in children. So far no safety profile has been published for this formulation. Hence in the present study acute toxicity study for Karappan ennai was carried out as per based on the OECD (Organization for Economic Co-operation and Development) Guidelines 402.Therefore, evaluating the toxic characteristics of a given substance is considered important for the protection of public health, since the exposure to the chemical is hazardous and can lead to adverse influences on the human body. The objective of this study is to evaluate the in vivo acute dermal toxicity of polyherbal formulation of Karappan ennai. The Karappan ennai at a dose of 15ml/kg and 30ml/kg of body weight did not produce treatment related signs of toxicity or mortality in all rats tested during the 14 day observation period. The results of this study suggest that the polyherbal formulation of Karappan ennai do not cause any apparent in vivo acute dermal toxicity study.

KEYWORDS: Karappan ennai, Siddha polyherbal formulation, OECD 402 guidelines, Karappan (Atopic dermatitis).

INTRODCTION

Traditional Indian system of Siddha medicine practiced over thousands of years. Has recently gained worldwide attention. Karappan ennai is a sastric siddha medicine. It is a polyherbal formulation chosen from the classic Siddha literary evidence of Agathiyar Vaithiya Vallathy 600. The medicine is indicated for skin diseases particularly atopic dermatitis in children. Atopic dermatitis[3] is allergic, non - contagious inflammatory skin disorder characterized by erythema, papules with oedema, intense pruritis, vesiculation, Oozing, crusting, Scaling and Lichenification. It affects 10 to 30% of the children worldwide and frequently occurs in families with other atopic diseases such as asthma, allergic rhinitis and food allergy.[4]

Till date, no safety profile is established for this formulation. Clinically no adverse drug reactions are reported so far. But to validate the safety of the drug scientifically, the present study was designed. A toxic property evaluation of toxic substances, particularly those obtained from plants, is considered to the protection of public health. In this present study, the evaluations of the use of the Karappan ennai for topical application were tested in acute dermal toxicity in rats.

MATERIALS AND METHODS

Acute dermal toxicity study of the study drug Karappan Ennai was carried out as per based on the OECD (Organization for Economic Co-operation and Development) guidelines 402.

Trial drug preparation

The fresh herbals of Karuppura valli, Siru cheruppadai, Erulli, Narimiratti, Cheppu nerunjil and vilakkennai was collected from Thiruvannamalai district 600 905, Tamilnadu, India.All the herbals were authenticated by the pharmacognosist, Siddha Central Research Institute(SCRI), Arumbakkam, Chennai 106, Tamilnadu, India.

All the herbals were purified as per the methods mentioned in Siddha literature.[5] The list of ingredients, their scientific names, part used and quantity are given in table 1 below.

Its ingredients and formulation composition are tabulated in Table 1.[6]

Tamil name	Botanical name[7]	Part used	Quantity(Lit.)
Karuppura valli	*Plectranthus ambonicus*	Whole plant	1.3 lit.
Siru cheruppadai	*Coldenia procumbens*	Whole plant	1.3 lit.
Eeruli	*Allium cepa*	Whole plant	1.3 lit.
Narimiratti	*Crotalaria verrucosa*	Whole plant	1.3 lit.
Cheppu nerunjil	*Indigofera enneaphylla*	Whole plant	1.3 lit.
Vilak-ennai	*Ricinus communis*	Seed oil	1.3 lit.

Method of preparation

The above mentioned ingredients were whole plant extracts are taken in a mud pot and boiled in a small flame. When the waxy consistency (Mezhugu patham) is obtained, the oil is taken out of the flame and cooled. Then preserved in a clean dry and air tight container.

Therapeutic usage

Karappan ennai are given topical application.
Externally: Oil is applied over the affected skin lesions.

Experimental animals

Eight-week old male and female Sprague Dawley rats with a body weight ranging from between 200 and 250 g were purchased from Biogen, Bangalore. Upon arrival, the rats were weighed and assigned randomly in polypropylene plastic cages, where one rat was placed in each cage with wood chips for bedding and housed in an animal room with controlled conditions involving these parameters; temperature (22±2°C), humidity (55±10%) and lighting (12 hours light/dark) in the animal house at C.L.Baid metha college of pharmacy, Chennai.

Skin preparation for dermal toxicity studies

Skin at the dorsal thoracic area of the rats was clipped under general ketamine (50 mg/kg) and xylazine (5 mg/kg) anaesthesia using an electric clipper, followed by manual shaving using razor blade. Based on OECD guidelines 402, not less than 10% of the body surface area was cleared for application of the test substance. The karappan ennai was applied to the dorsum area.

Experimental design

In acute dermal toxicity studies, the toxic effects of the karappan ennai in Sprague Dawley rats were examined at dosage of 15ml/kg body weight for a period of 14 days for acute dermal toxicity study based on the OECD guidelines 402, respectively.

Based on (OECD) guidelines, female rats are used in acute toxicity studies as they are more sensitive to toxic substance than male.

The application of the karappan ennai in acute toxicity study occurred once. In acute dermal toxicity, a total number of 06, eight-week old female Sprague Dawley rats were divided (n=6).
The duration of this study was 14 days. Each group underwent application of the Karappan ennai once at a day 1 and sacrificed at 14 day of the experimental period.

General sign and behavior of the rats

The toxic effects of polyherbal formulation of Karappan ennai on the appearance and the general behavioral pattern of the rats are shown in Table 2 and Table 3, respectively.

Table 2: Mortality rate of rats after applied with topical application of Karappan ennai at 15ml/kg and 30ml/kg once, for the acute dermal toxicity study.

Group	*Mortality rate (%)
G1	0
G2	0
G3	0
G4	0

*Mortality rate is number of dead rats divided by total number of tats per group
G1: No treatment, G2: Paraffin, G3: K.ennai 15ml/kg, G4: K.ennai 30ml/kg

Table 3: Behavioral patterns and general appearance of rats in all groups.

Abnormal sign	Control group G1 (6hr)	Control group G2 14hr)	Treatment group G2- G4(6hr)	Treatment group G2-G4(14hr)
Skin effects	Normal	Normal	Normal	Normal
Mucous membrane	Normal	Normal	Normal	Normal
Behavioral patterns	Normal	Normal	Normal	Normal
Salivation	Normal	Normal	Normal	Normal
Sleep	Normal	Normal	Normal	Normal
Lethargy	Normal	Normal	Normal	Normal
Eyes	Normal	Normal	Normal	Normal

G1: No treatment, G2: Paraffin, G3: K.ennai 15ml/kg, G4: K.ennai 30ml/kg

No toxic signs or mortality were observed in any animals, which survived up to 14 days after applying of the extracts once on the first day at single dose level of 15ml/kg and 30ml/kg body weight. The behavioral patterns of animals were observed first 6 hours and 14 hours after applying the Karappan ennai. The animals in the treated group was normal and did not display significant changes in behavior, skin effects, breathing, impairment in food intake and water consumption, postural abnormalities and hair loss. The animal in both vehicle treated and Karappan ennai treated groups were normal.

Inference

Results in this study indicated no signs of Acute Dermal toxicity[8] (402 OECD Guidelines) in rats.

DISCUSSION

A drug which is intended to be used therapeutically in humans should be subjected to toxicity studies for safety concern. The study drug Karappan ennai has been in use for skin diseases and so far no adverse reaction are reported. But, to have documentary evidence the acute dermal toxicity was conducted. In acute dermal toxicity, a dose 15ml/kg and 30ml/kg was administered. The observation were made for 14 days. Here, in this study there was no significant difference was noted in body weight of experimental group and when compared to normal control group. Though there are reports of acute dermal toxicity on ingredients of Karappan ennai, the polyherbal formulation as a whole is safe in rats.

CONCLUSION

From the above observations, it is clear that the drug Karappan ennai is non –toxic at the dose 15ml/kg and 30ml/kg body weight in rats reveals that the drug has no adverse effects, so it is safe to human beings. Nowadays, In Atopic dermatitis most commonly prescribed medication are topical steroids can have potential side effects. But, sastric Siddha polyherbal formulation is safety and effective in skin diseases. This results contribute towards the therapeutic role in the treatment of karappan (Atopic dermatitis in children).

REFERENCE

1. Agathiyar vaithya vallathy-600(moolamum uraium). 2nd ed. New delhi: Central council for research in ayurvedha and siddha, 2005; 123.
2. Murugesa mudhaliar k s. kuzhanthai maruthuvam (bala vagadam).5th ed. Indian medicine and homeopathy pub, 2010; 355.
3. O.P.Ghai-Essential Pediatrics.OP Ghai, Ghai essential pediatrics 7th edition, CBS Publishers, 7th Edition. Page No.668 The wealth of India. Richard e. Behrman, 2010.
4. Nelson text book of pediatrics. 14th ed. w.b.saunders company; 596. Old hiambo JA, Willians HC, Clayton TO et al: Global variations in prevalence of eczema symptoms in children from ISAAC phase Three. J Allergy clin immunol, 2009; 124: 125-1258.
5. S.Kannu samipillai, sigicha rathna deepam sarakku suthimuraigal, Indian medicine and homeopathy, Arumbkkam, Chennai, 1st edition edition, 1991.
6. Murugesa mudhaliyar K S, Siddha Materia Medica (Medicinal plant Division). 2nd ed. Chennai: Indian medicine and homeopathy pub, 2008; 131,484,833,323,479,74.
7. S. sankaranarayanan, Medicinal taxonomy of angiosperms, 3rd edition.
8. Toxicologial Screening of Karappan ennai, C.L.Baid metha college of Pharmacy, IAEC No: LI/21/CLBMCP/2017, OECD 402, Thoraipakkam, Chennai-97, Tamilnadu, India.