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Acute oral toxicity evaluation of Kandankathiri Legiyam in Swiss albino mice: A preclinical safety assessment

Praveenashri. P[1], A. Kavipriya[1], T. R. Siddique Ali[2], D. Sasikumar[3]

[1]PG Scholar, PG Department of Varmam Maruthuvam, Government Siddha Medical College, Chennai

[2]Professor, Head of the Department, PG Department of Varmam Maruthuvam, Government Siddha Medical College, Chennai

[3]Lecturer, PG Department of Varmam Maruthuvam, Government Siddha Medical College, Chennai

*Address for Correspondence: **Praveenashri .P**

PG Scholar, Department of Varmam Maruthuvam

Government Siddha Medical College, Chennai

E Mail: *drpraveenashri2303@gmail.com*

Abstract

Background: Kandankathiri Legiyam is a classical Siddha polyherbal formulation traditionally used for treating gynecological disorders, including Polycystic Ovarian Disease (PCOD). Scientific evaluation of its safety is essential to support its therapeutic use.

Objective: To assess the acute oral toxicity and safety profile of Kandankathiri Legiyam in mice following standard toxicological guidelines.

Materials and Methods: An acute oral toxicity study was conducted in healthy adult female albino mice in accordance with OECD guideline 423/425. The animals were administered a single oral dose of Kandankathiri Legiyam at graded levels, including a limit dose of 2000 mg/kg body weight. The formulation was suspended in a suitable vehicle and given after overnight fasting. The animals were observed individually during the first 4–6 hours post-dosing and daily for 14 days for clinical signs of toxicity, behavioral changes, morbidity, and mortality. Body weight, food intake, and water consumption were monitored periodically. At the end of the observation period, all animals were subjected to gross necropsy for evaluation of vital organs.

Results: No mortality or treatment-related toxic signs were observed in any of the mice throughout the study period. The animals showed normal behavioral patterns, with no significant changes in body weight, food intake, or water consumption. Gross pathological examination of major organs such as liver, kidney, heart, and lungs did not reveal any abnormalities.

Conclusion: Kandankathiri Legiyam did not produce any signs of acute toxicity in mice up to the dose of 2000 mg/kg body weight. The median lethal dose (LD_{50}) is therefore considered to be greater than 2000 mg/kg, indicating that the formulation is relatively safe and can be further evaluated for its therapeutic efficacy in PCOD.

Keywords: Kandankathiri Legiyam, Acute oral toxicity, Mice, OECD guidelines, Siddha medicine, PCOD

1. Introduction

Polycystic Ovarian Disease (PCOD) is one of the most prevalent endocrine disorders affecting women of reproductive age worldwide. The condition is characterized by chronic anovulation, hyperandrogenism, insulin resistance, obesity, and infertility[2,3]. PCOD significantly impacts reproductive, metabolic , psychological health and remains a major public health concern.

Current treatment modalities include hormonal therapy, insulin sensitizers, and ovulation induction agents. However, long-term pharmacological interventions may be associated with adverse effects and recurrence of symptoms[2,3].Consequently, there is increasing interest in traditional systems of medicine for safer and more holistic therapeutic options.

Siddha medicine, one of the oldest traditional medical systems practiced in South India, describes several herbal formulations for reproductive and metabolic disorders. Kandankathiri Legiyam is a classical polyherbal preparation containing Kandankathiri (*Solanum xanthocarpum*) along with several medicinal herbs. These ingredients possess antioxidant, anti-inflammatory, digestive, and metabolic regulatory properties [4].

Before undertaking pharmacological and clinical investigations, it is essential to establish the safety profile of the formulation. Acute oral toxicity studies provide valuable information regarding the toxicological characteristics of a substance and assist in dose selection for subsequent studies [5,6].

IEC Approval

The Institutional Ethical Committee, Government Siddha Medical College, Chennai Reviewed And Approved The Study.

IEC No: GSMC-CH-1243/ME-II/092/2024

CTRI No: This trial was registered in Clinical Trial Registry India

CTRI No: CTRI/2025/05/087836

Acute oral toxicity:

The Organization for Economic Co-operation and Development (OECD) guidelines for testing of chemicals, No 425

IAEC approval: MB/IAEC/25/02/09/A

2. Materials and Methods

2.1 Study Drug

Drug: Kandankathiri Legiyam

System: Siddha medicine

2.2 Composition of Kandankathiri Legiyam

S.No	Ingredients	Quantity
1	Kandankathiri	3500 g
2	Sukku	35 g
3	Milagu	35 g
4	Thippili	35 g
5	Kadukkai	35 g
6	Nellikai	35 g
7	Thanrikkai	35 g
8	Omam	35 g
9	Kurosaniomam	35 g
10	Vaividangam	35 g
11	Lavangapattai	35 g
12	Seeragam	35 g
13	Narukkumoolam	35 g
14	Yanaithippili	35 g
15	Kostam	35 g
16	Thalisapathiri	35 g
17	Akkragaram	35 g
18	Panaivellam	1400 g
19	Thaen	325 ml
20	Pasunei	325 ml
21	Thanneer	21.5 L
22	Pasum pal	1.3 L

2.2 Test Substance

Test Substance Name : Kandangkathiri legiyam
Purity : NA
Batch No : Nil
Date of Manufacture : NA
Physical Appearance : herbal paste
Storage Conditions : 24±30 °C

Test System

Species : Mice (Mus musculus)
Strain : Swiss Albino
Body weight Range : 30-/+5gm
Age : 4-8 weeks
Sex : Female
Animal Source : Mass Biotech.
Number of Animals : Three nulliparous and non-pregnant female mice
Method of Identification : Colour code on body tail and cage number

2.3 Experimental Animals

- Species: Swiss albino mice
- Sex: Female
- Number: 3
- Dose: 2000 mg/kg body weight orally by gavage

Animals were maintained under standard laboratory conditions.

2.4 Study Design

Single dose of drug was administered to Swiss Albino mice by oral route at 48 hour intervals. As no toxicity information on the test substance was available, the starting dose of 2000 mg/kg body weight was selected and administered to first animal and subsequentanimals were given higher doses (2000 mg/kg. b.wt) depending on the survival of the previous animal.

The final stopping criterion was, the upper testing bound at which three consecutive animals survived. All animals were fasted approximately 15 to 16 hours prior to dosing. Clinical observations were performed pre-dose, at 30 minutes, 1, 2, 3 and 6 hour post dosing and daily for fourteen days to assess survival and general condition. On day14, gross pathological examination was performed on all animals.

Summary of experimental design is presented below:

Mice N^o	Dose (mg/kg b.wt.)	Route	Volume (ml/kg)	Concentration (mg/ml)	Treatment Day	N° of doses	Day of Sacrifice
3	2000	Oral	10	60	1	1	14

2.5 Dose Preparation and Administration

The test substance was administered orally to mice by gavage at a dose of 2000 mg/kg body weight. Dose volume was maintained as 10 ml/kg body weight. The animals were administered a single dose of test substance by gavage using a stainless steel blunt tipped cannula (size 22G) attached to a Boro-silicate hard glass syringe, which was graduated up to 1 ml.

2.6 Parameters assessed included:

- Mortality and morbidity
- Clinical signs of toxicity
- Body weight
- Feed consumption
- Body temperature
- Gross pathological changes

Observation

Mortality

Animals were observed at least twice per day for mortality and morbidity.

Clinical Observations

Clinical observations were performed pre - treatment and at 30 minutes, 1, 2, 3 and 6 hour after oral intubation on the day of dosing. Subsequently, the animals were observed once daily for 14 days after dosing.

Body weight

All animals were weighed prior to dose administration (day 1) and on Day 7 and on Day 14after dosing.

Feed Measurement

Feed for the animals were weighed and given on day 1 ,4,8,12 and on Day 14 after dosing.

Temperature

All animals were temperature value is measured by infrared thermometer of point of care company which measures up to range of (89°F-109°F) noted on Day1 on Day7 on Day14 after dosing

Gross Pathology

At the end of 14 day observation period, all animals were euthanized by using isoflurane asphyxiation technique and were subjected to gross pathological examination that included examination of the external surface of the body, all orifices, thoracic and abdominal cavities and their contents. The appearance of macroscopic abnormalities was recorded, if any.

3. Results and Interpretation

Table 1. Summary of Clinical Observations and Moralities

Observation	Dose(2000mg/kg body weight)
Clinical signs	
Normal	3/3
Lethargy	0/3
Abdominal breathing	0/3
Piloerection	0/3
Mortality	0/3

Appendix 1. Clinical Observations of Individual Animals

Dose (mg/kg b.wt.)	Mice Nº	Clinical Signs Observed after Dosing																	
		30 min.	At Hour (Day0)			On Day													
			1	2	3	*	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2000	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Key: 0 =Normal
*=Observation made at 6h after oral dose

Appendix 2. Body weight and Body weight gain of Individual Animals

Dose (mg/kg b.wt)	Gender	Mice N°	Body weight (g) on day		
			#	7	14
2000	F	1	32	30	30
		2	27	27	30
		3	37	37	36

Key : #=Before dosing(Day-0), F=Female

Appendix 3. Feed Measurement of Individual Animals

Dose	Days	Feed input	Feed remaining	Feed consumed	Feed consumed/ (animal/day)
2000 mg/kg	1	60			
	4	60	3	57	4.7
	8	60	6	54	4.5
	12	60	4	56	4.6
	14	60	8	52	4.3

Appendix 4. Temperature of each mice in every group (Fahrenheit)

Mice N°	Temperature on day (Fahrenheit)		
	#	7	14
1	99.6	93.2	91.8
2	98.2	98.6	97.3
3	96.9	96.2	96.3

Key : #=Before dosing(Day-0)

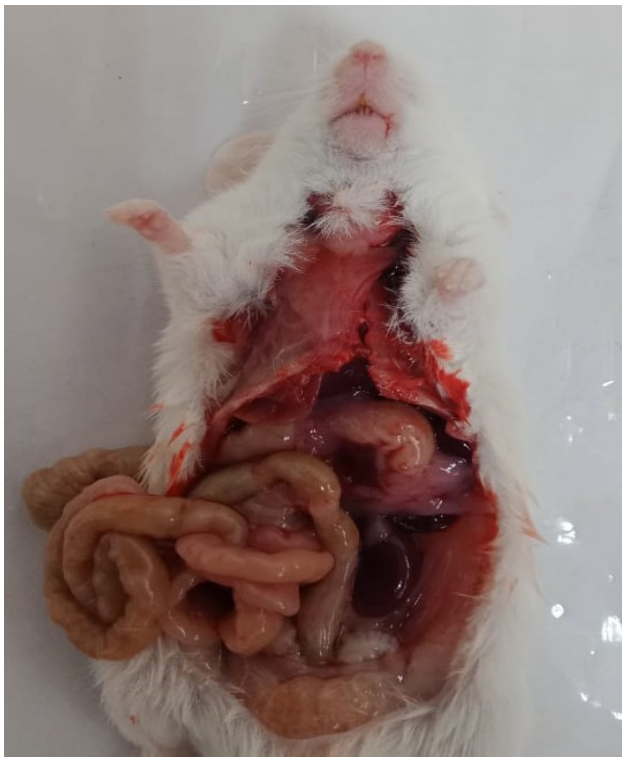
Appendix 5. Gross Pathological Findings of Individual Animals

Mice N^{o}	Dose (mg/kgb.wt.)	Mode of Death	Gross Pathological Findings	
			External	Internal
1	2000	TS	NAD	NAD
2	2000	TS	NAD	NAD
3	2000	TS	NAD	NAD

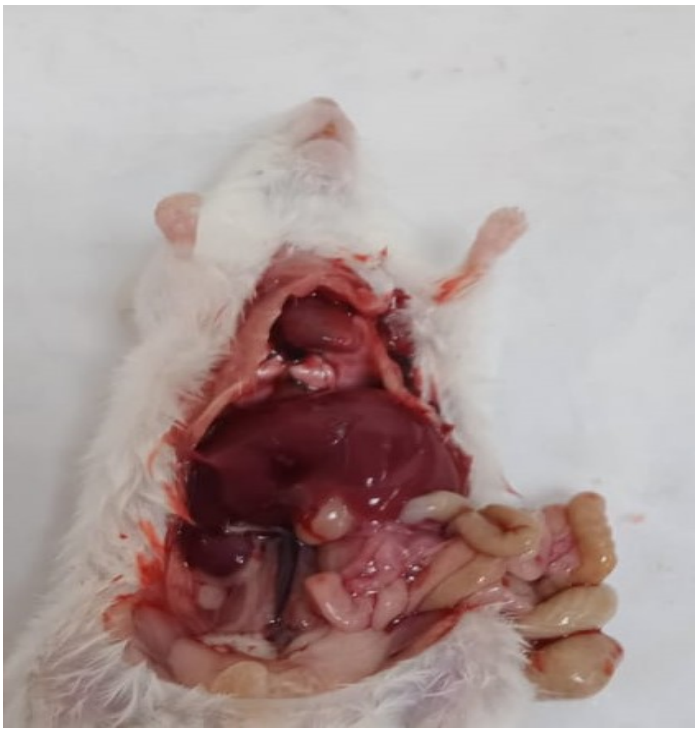
Key: F=Female, NAD=No abnormal , TS= terminal sacrifice

Appendix 5. Gross Pathological Findings of Individual Animals

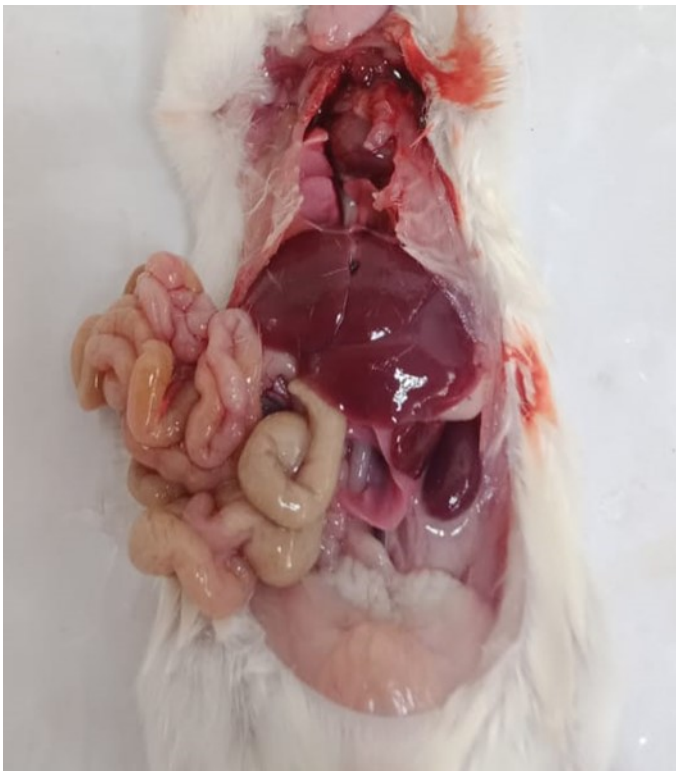
Gross Pathology of mice 1 of 2000 mg/kg b.wt



Gross Pathology of mice 2 of 2000 mg/kg b.wt



Gross Pathology of mice 3 of 2000 mg/kg b.wt



4. Discussion

Acute toxicity studies provide fundamental information regarding the safety profile of herbal formulations. In the present investigation, oral administration of Kandankathiri Legiyam at 2000 mg/kg body weight did not produce mortality or observable toxic signs in Swiss albino mice.[5][6]

The absence of clinical symptoms such as lethargy, piloerection, respiratory distress, and behavioral abnormalities suggests that the formulation does not exert acute neurotoxic or systemic toxic effects at the tested dose. Furthermore, maintenance of normal feed intake and body weight indicates preservation of physiological and metabolic functions.[7]

Gross pathological examination did not reveal any treatment-related abnormalities, suggesting that major organs were not adversely affected by the formulation.[4] The favorable safety profile observed in this study may be attributed to the traditional use and herbal composition of Kandankathiri Legiyam.

According to OECD guideline 425, absence of mortality at 2000 mg/kg indicates a low level of acute toxicity and suggests that the LD50 is greater than 2000 mg/kg body weight.

5. Conclusion

The present study demonstrated that Kandankathiri Legiyam did not produce mortality, toxic clinical signs, or gross pathological abnormalities following a single oral administration of 2000 mg/kg body weight in Swiss albino mice.

The median lethal dose (LD50) was estimated to be greater than 2000 mg/kg body weight, indicating that the formulation possesses a favorable acute safety profile. These findings support further pharmacological and preclinical investigations of Kandankathiri Legiyam for the management of Polycystic Ovarian Disease.

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