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Research Article

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Acute oral toxicity study of polyherbal formulation Kurunthotti Kudineer

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Abstract

The current study was designed to study acute oral toxicity study of Polyherbal formulation Kurunthotti kudineer according to WHO guidelines. 20 Wister albino rats were used for the study. Kurunthotti Kudineer in single oral doses was supplemented to all rats. The parameters like general appearance, behaviour, bodyweight, mortality& necropsy were studied. No change in general appearance and mortality was observed. Kurunthotti Kudineer was found to be safe at dose of 5000mg/kg.

Keywords: Kurunthotti Kudineer, Wister albino rats, WHO, Acute oral toxicity

1. Introduction

Traditional and alternative medicine is extensively practiced in the prevention, diagnosis, and treatment of various diseases[(1)] [(2)]. The Polyherbal drug, Kurunthotti Kudineer in Siddha literature, which is indicated Vatha disease. Despite the widespread use of plants for treatment of several ailments there is a little known about their toxicity and safety. The evaluation of the toxic action of the plant extracts or herbal formulations is important in order to consider them safe before used as medicines[(3)].A key stage in ensuring the safety of drugs is to conduct toxicity tests in appropriate animal models[(4)]. The objective of the current experiment was to study the Acute toxicity of trial drug Kurunthotti Kudineer consists of six raw drugs namely Kurunthotti ver (*Sida rhomphoidus*), Thazhuthazhai ver (*Clerodendrum phlomidis*), Mahil (*Mimusop elengi*), Naagaram (*Zingiber officinalae*), Maruvu (*Majorana hortensis*), Devatharam (*Cedrus deodara*) and also cost effective. In the present study the acute oral toxocity study of the Kurunthotti Kudineer was investigated to assess its safety and tolerability profile in long term treatment[(5)].

2. Materials and Methods

The following *in vivo* toxicity studies were carried out on by Kurunthotti Kudineer (KK) World Health Organization (WHO) guidelines. The Acute Oral toxicity studies were carried out at National Institute of Siddha. The study was done after getting permission from the Institutional Animal Ethical Committee. IAEC Approved No: For acute toxicity study – NIS/IAEC-IV/07/05012017.For Acute toxicity studies test animals were obtained from Tamil Nadu Veterinary and Animal Sciences University, Madhavaram. Animals are kept at animal house, National Institute of Siddha, Chennai.

2.1 Description of the Method

Animals were selected as per guidelines. Healthy adult animals of Wister albino rat, both male and female sex were used for acute oral toxicity study. The female animals used in the studies were nulliparous and non-pregnant.

2.2 Housing and feeding conditions

The temperature in the experimental animal room: 22ºC (± 3ºC)

Humidity: 60 ± 10 %

Lighting : Artificial, the sequence being 12 hours light, 12 hours dark.

The animals were housed in polypropylene cages provided with bedding of husk. The animals had free access to RO water. For feeding, Standard pellet diet (bought from Sai Meera foods pvt. Ltd, Bangalore) was used.

2.3 Preparation of Selection of the animals

The animals are randomly selected, to permit individual identification by cage number and individual marking on the fur of each animal was made with picric acid. The animals were kept in their cages for 7 days prior to dosing to allow for acclimatization to the laboratory conditions. The principles of laboratory animal care were followed.

2.4 Test Substance

Kurunthotti Kudineer (KK) is pale yellowish in colour, free flowing- greasy and slightly pungent. Oral route was selected, because it is the normal route of clinical administration.

2.5 Acute Oral Toxicity Study

Table 1: Experimental Animals:

1.	Species and strain	Wister Albino rat
2.	Sex	Male and Female
3.	Age, Weight	6-8 weeks, 150-175 gm
4.	Test guideline	WHO guideline
5.	Groups/treatment	Grouped by randomization
6.	Duration of exposure to the Kurunthotti Kudineer	Single dose
7.	Study duration	14 days
8.	Number of animals	10 male, 10 female
9.	Route of administration	Oral

2.6 Number of animals and dose levels

Animals are divided into two groups, each group containing 5 male and 5 female rats. One group as control and the other as test group. Control group is treated with Palm sugar and other groups were treated with test drug Kurunthotti Kudineer (KK) ten times the therapeutic dose (5000mg per kg b.wt).

Table 2: Groups No. of Rats

Group I Vehicle control (Palm sugar)	5 male, 5 female
Group II Test drug – Kurunthotti Kudineer (KK) (5000mg per kg b.wt)	5 male, 5 female

2.7 Administration of doses

The test drug was administered in a single dose by using oral gavage. Animals were fasted prior to drug administration. Following the period of fasting, the animals were weighed and test drug was administered. The control groups received equal volume saline. The test drug was administered at 10 times the therapeutic dose (5000 mg per kg b.wt). The food was withheld for 3-4 hours after dosing the animal. Observations were made and recorded systematically and continuously observed after the substance administration as per the guidelines.

- ½ hour, 1 hour, 2 hours, 4 hours and up to 24 hours observation
- All rats were observed twice daily for 14 days
- Body weight were Calculated weekly once
- Feed & water intake were Calculated daily

2.8 Cage side observation

The animals were monitored for behavioural parameters like Alertness, Aggressiveness, piloerection, Grooming, Gripping, Touch Response, Motor Activity, Tremors, Convulsions, Muscle Spasm, Catatonia, Muscle relaxant, Hypnosis Analgesia, Lacrimation, Exophthalmus, Diarrhoea, Writhing, Respiration, Mortality

2.9 Gross Necropsy

At the end of the 14thday, all the animals were sacrificed by using the injection of Pentothal sodium. Gross necropsy includes examinations of the external surface of the body, all orifices, cranial, thoracic and abdominal cavities and their contents brain, eye, lungs, heart, spleen, liver, kidneys, adrenals, uterus of all animals.

3. Results and Discussion

Acute oral toxicity studies of internal medicine Kurunthotti Kudineer were also been studied. The ingredient in Kurunthotti kudineer drug said to possess Anti Vatha, Anti arthritic stimulant, carminative, antispasmodic, Immunomodulatary, Anti-oxidant, anti-inflammatory, anti-histamine actions and also cost effective.

Table 3: Behavioural Signs of Acute toxicity Study of Kurunthotti kudineer.

Parameters	30 mints		4 hrs		24 hrs		1st week		2nd week	
	C	E	C	E	C	E	C	E	C	E
Skin & Fur	N	N	N	N	N	N	N	N	N	N
Mucous Membrane	N	N	N	N	N	N	N	N	N	N
Respiratory rate	N	N	N	N	N	N	N	N	N	N
Heart rate	N	N	N	N	N	N	N	N	N	N
Salivation & Lacrimation	N	N	N	N	N	N	N	N	N	N
Lethargy	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
Piloerection	N	N	N	N	N	N	N	N	N	N
Urinary incontinence	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
Defecation	N	N	N	N	N	N	N	N	N	N
Sleep & Gait	N	N	N	N	N	N	N	N	N	N
Tremors &Convulsion	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
Mortality	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL

N – Normal, C – control, E – Experimental

All the data were summarized in the form of revealed that there was no abnormal signs and behavioural changes in all animals at the dose level of 5,000 mg/kg body weight administered orally, during the study period. There was no mortality observed after dosing of Kurunthotti Kudineer upto 5000mg/kg body weight during the study period of 14 days. This indicates that the LD50 of Kurunthotti Kudineer is more than 5000mg/kg b.wt. There were no changes in skin and fur, eyes and mucous membranes of all animals. The eating, drinking habit, sleep pattern, locomotion were normal in all animals and no changes in body weight as compared to control group. At the end of the 14 the day, necropsy was performed and there was no abnormality seen in test groups as compared to control group during the examination.

4. Conclusion

The study revealed that Kurunthotti Kudineer polyherbal formulation practically non-lethal after an acute exposure. The median lethal dose (LD_{50}) of Kurunthotti Kudineer using fixed dose procedure is greater than 5000 mg/kg. All the three animals survived by the end of the study, Clinical signs symptoms and gross necropsy did not reveal any major findings. Hence it is practically nontoxic.

5. References

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