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# Acute Toxicity Profiling of Siddha Drug Oma Kudineer in Wistar Rats

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**Keywords:** Oma kudineer, acute toxicity, acute nasopharyngitis, oral route

**ABSTRACT**

Siddha system of Medicine which has been prevalent in ancient Tamil land is the foremost of all another medical system in the world. It is a comprehensive system that places equal emphasis on the body, mind and spirit and strives to restore the initiate harmony of the individual. It is practiced in south India especially in Tamil Nadu. In this system, first preference is given to herbs based medicine. Herbal drugs have been a part of the evolution of human health care for thousands of years in India. Oma kudineer is prepared as per mentioned in classical siddha pediatric textbook named Balavagadam. It is a polyherbal drug. Before conducting clinical trial, preclinical study should be undergone as per WHO guidelines. The present preclinical study aimed to carry out safety and toxicity of Oma kudineer. Healthy adult Wistar albino rats weighing between 170-200 g were used for this study. Acute toxicity studies were carried out as per OECD guidelines 423. Hematological parameters, biochemical parameters, histopathological study were performed for all animals. The dose utilized for evaluation of acute toxicity study is about 2000 mg/kg higher than that of the therapeutic dose. The study concludes that on oral administration of the above dose level to female Wistar rats, there were no characteristic clinical signs of toxicity or mortality or severe toxicological effects on selected body organs, biochemical indices and hematological and histopathological markers of rats during the acute periods of study was observed.

## INTRODUCTION

Acute nasopharyngitis is commonly known as cold, coryza, is highly contagious, infection of the upper respiratory infection system. Common symptoms include running nose, fever, cough and sore throat. The common cold is the most frequent infectious disease in humans. The average adult gets two to four colds a year, while the average child may get six to eight infections. They occur more commonly during the winter.

It has both infective and noninfective cause. Noninfective cause like allergic to food, low socio-economic status, dust allergy, environmental changes like pollution, climate change and family history can cause nasopharyngitis. A virus or bacteria causes infective nasopharyngitis. Although viruses causes most acute nasopharyngitis episodes, group A streptococcus causes 37% of infection in children older than 5 years, other bacterial causes of infection is group C streptococcus (5%), anaerobic species (1%). Among viruses; Rhinovirus, Corna virus and Adenovirus account for the 30% of total case. It can spread through tiny air droplets that are expelled when a person infected sneezes.

In siddha pediatric book balavagadam, Neer kana maantham has symptoms similar to common cold. Hence, we compared it with acute nasopharyngitis. Oma kudineer is polyherbal drug used in its treatment. So prior to using this drug in humans, safety of the drug has to be proved. Preclinical study is important to determine a safe dose for human trial. The present preclinical study is aimed to evaluate the acute toxicity of Oma kudineer. This study provides vital information about efficacy and safety of this drug.

## MATERIALS AND METHODS

### SOP OF OMA KUDINEER

Oma kudineer is a polyherbal formulation comprising of 4 herbs omam (*Carum copticum*), pepper *(Piper nigrum*), long pepper *(Piper longum*) and garlic *(Allium sativum*). All the drugs were taken in equal ratio purified and grinded to the powder form. Required quantity was taken from the grinded powder and mixed with pure water and this mixture was boiled until the concentrated decotation of the ingredient was obtained.

**Acute Toxicity Study**

Acute toxicity study of the study drug Oma Kudineer was carried out as per OECD guideline (Organization for Economic Co-operation and Development) Guideline-423. The animals fasted overnight with free access to water. The study was conducted with single oral dose administration of Oma Kudineer.

**Animal**

Healthy adult Wistar albino rats weighing between 170-200 g were used for the study. The animals were housed in polypropylene cages and were kept in well ventilated with 100% fresh air by air handling unit (AHU). A 12 light/dark cycle was maintained. Room temperature was maintained between 22±2$^0$C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study.

The experimental protocol was approved by the Institutional Animal Ethics Committee of SathyabamaUniversity,Chennai, Tamil Nadu, India (IAECSU/CLATR/IAEC/VII/040/2016).

**Animal Grouping**

One group consisting of 6 female rats was used for this study. The dose utilized for evaluation of acute toxicity study is about 2000 mg/kg higher than that of the therapeutic dose.

**GROUP I**: Animals received test drug 2000 mg/kg (p.o)

The animals were fasted overnight (12-16 hrs) with free access to water. The study was conducted with single oral administration of study drug Oma Kudineer 2000mg/kg (p.o). The animals were observed continuously for first 72 h and then 14 days for emerging signs of behavioral changes, body weight changes and for mortality.

Occurrence of toxicity in animals was observed continuously for the first 4 to 24 h and observed periodically for the next 14 days. Observation includes the change in skin, fur, eyes and mucus membrane. Appearance of CNS, CVS and ANS related toxicity such as tremors, convulsions, sedation, steric behavior, respiratory distress, cardiovascular collapse, response

to sensory stimuli, salivation, diarrhea, lethargy, sleep, coma and mortality were observed with special attention.

Body weight was recorded periodically. At the end of the experiment, all animals were subjected for gross necropsy and observed for pathological changes.

**Statistical analysis**

The statistical analysis was carried by one way ANOVA (GRAPH PAD PRISM 5 computer program). Results were expressed as mean ± standard error. A statistical comparison was carried out using the Dunnet's test for the control and treatment group.

**DRUG DOSING**

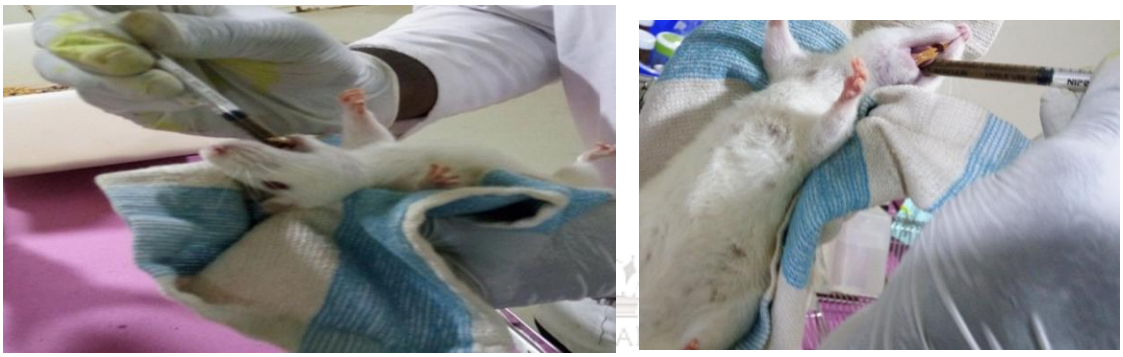

**Fig 1: Oral drug administration**

**Fecal Pellet Analysis**

**Methodology**

Rats of control and treatment group were allowed to explore to open field on clean and sterile Stainless steel tray. The collected pellets were analyzed for consistency, color, shape, presence of blood cells, etc.

**Fig 2: Fecal Pellet Analysis**

**Table 1: Fecal Pellet Analysis**

| Analysis | Group I |
|---|---|
| **Consistency** | Soft Pasty |
| **Shape** | Irregular |
| **Colour** | Pale brownish |
| **Mucous Shedding** | Absence |
| **Blood Cells** | Absent |
| **Signs of Infection** | None Observed |

**Muscle Grip Strength Analysis**

The grip strength test is a simple non-invasive method designed to evaluate rat muscle force in vivo. Rats of control and drug treated group were allowed to hold the pull bar with both the hind limbs firmly then the animal was gently pulled back with the tail until the animal lost the grip toward the bar. The procedure was repeated to get the average value. Muscle grip strength of the drug treated group was compared to that of the control rat to ensure the change in coordination.

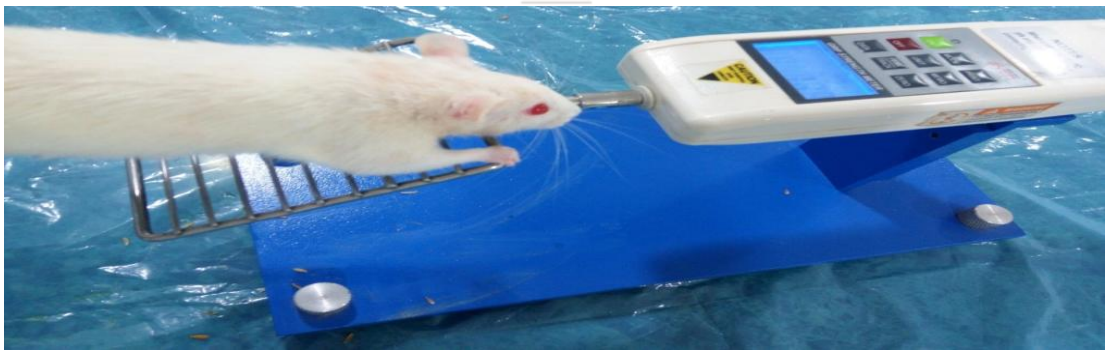

**Fig 3: Muscle Grip Strength Analysis**

**Metabolic Cage for Urine Collection**

Rat of control and treatment group was placed individually in metabolic cage with free access to feed and water. Urine dropping from the animal was collected using specialized wire mesh system fixed at the base of the cage having provision to trap the fecal pellet mixed with urine sample. The collected urine sample was subjected to analysis with respect to colour, pH, glucose, ketone bodies, pus and blood cells.

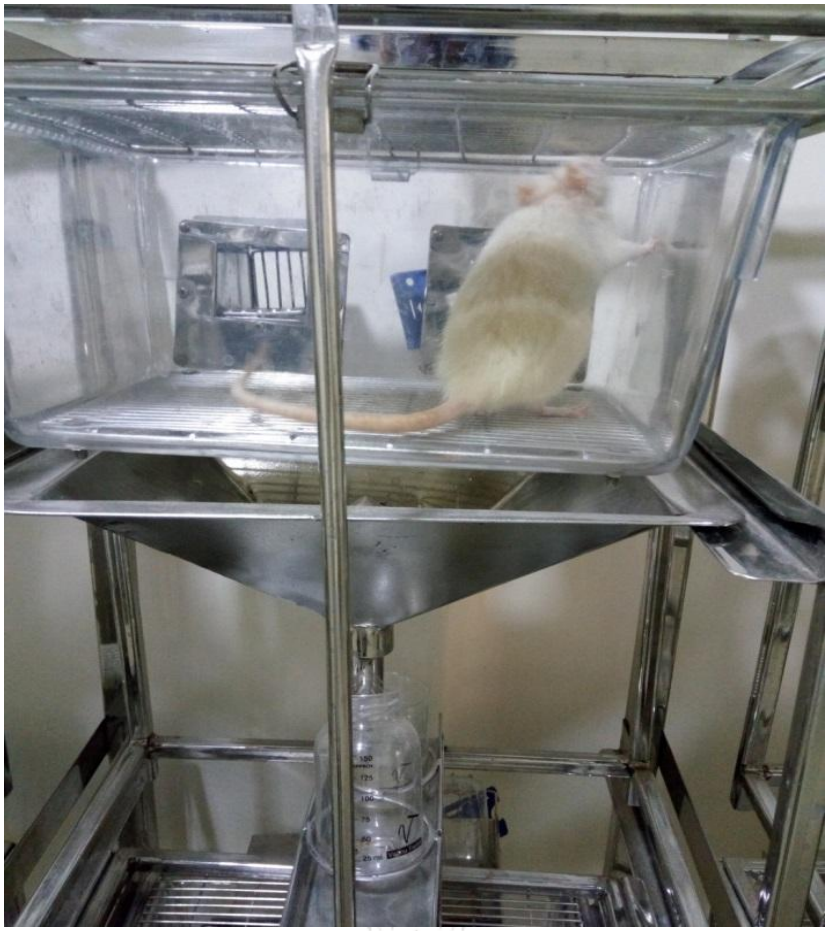

**Fig 4: Metabolic Cage for Urine Collection**

## RESULTS

Table 2: Assessment of clinical signs in rats treated with Oma Kudineer on Acute toxicity study

| **Acute toxicity study** | |
|---|---|
| **Parameter** | **Group I** |
| **Clinical Signs Parameters for the duration of 14 days** | **Test Drug 2000mg/kg** |
| **Number of animals observed** | 6 Female |
| **Lacrimation** | Absence |
| **Salivation** | Absence |
| **Animal appearance** | Normal |
| **Tonic Movement** | Absence |
| **Clonic Movement** | Absence |

| | |
|---|---|
| **Laxative action** | Moderate |
| **Touch Response** | Normal |
| **Response to Sound** | Normal Response |
| **Response to Light** | Normal Response |
| **Mobility** | Normal Response |
| **Respiratory Distress** | Nil |
| **Skin Color** | Normal |
| **Stereotype behaviour** | Absence |
| **Piloerection** | Absence |
| **Limb Paralysis** | Absence |
| **Posture** | Normal |
| **Open field behaviour** | Normal |
| **Giat Balancing** | Normal |
| **Freezing Behaviour** | Absent |
| **Signs of Stress and Anxiety** | None Observed |
| **Muscular coordination** | Normal |
| **Muscle grip** | Normal |
| **Sedation** | Absence |
| **Social Behavior** | Normal |
| **Urine Analysis** | No Abnormality |
| **Urine Colour** | Yellowish |
| **Urine Ph** | 6 |
| **Urine -Glucose** | Absence |
| **Urine -Ketones** | Absence |
| **Urine- Bilirubin** | Absence |
| **Urine-Blood Cells** | Negative |
| **Urine - Pus cells** | Negative |
| **Mortality** | Nil |

**Table 3: Quantitative data on the body weight of rats treated with Oma Kudineer in Acute toxicity study**

| Group I | Before Treatment Weight in Gms | After Treatment Weight in Gms |
|---|---|---|
| Mean | 179.5 | 188.8 |
| Std. Deviation | 4.80 | 5.776 |
| Std. Error | 1.962 | 2.358 |

Values are mean ± S.D (n = 6 per group). Statistical significance carried out using one way ANOVA followed by Dunnett's test.

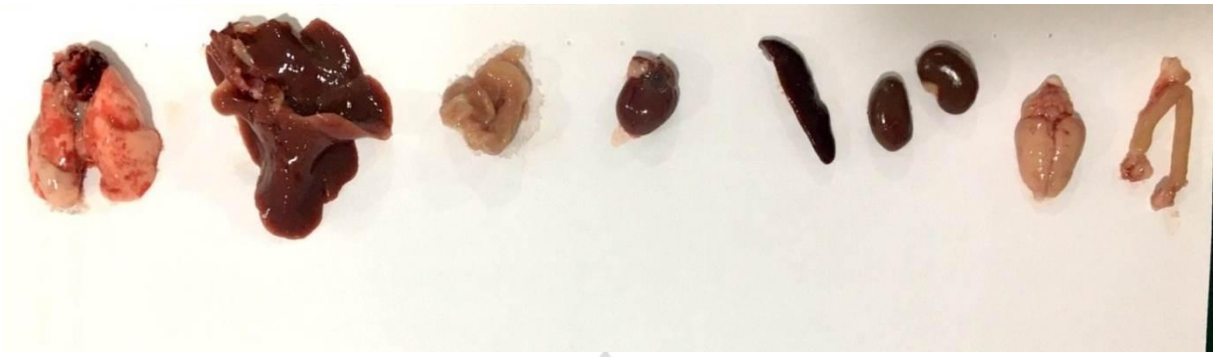

**Fig 5: Organ Gross Observation of rats treated with Oma Kudineer in Acute toxicity study**

**Table 4: Quantitative data on absolute organ weight of rats treated with Oma Kudineer in Acute toxicity study**

| Group I Acute Toxicity Study | HEART (gms) | LIVER (gms) | KIDNEYS (gms) | SPLEEN (gms) | BRAIN (gms) | LUNG (gms) | STOMACH (gms) | UTERUS & OVARY (gms) |
|---|---|---|---|---|---|---|---|---|
| Mean | 0.5917 | 5.182 | 1.55 | 0.7 | 1.517 | 1.633 | 0.8333 | 1.417 |
| Std. Deviation | 0.1436 | 1.022 | 0.1643 | 0.1549 | 0.2317 | 0.2422 | 0.2875 | 0.1329 |
| Std. Error | 0.05862 | 0.4171 | 0.06708 | 0.06325 | 0.09458 | 0.09888 | 0.1174 | 0.05426 |

Values are mean ± S.D (n = 6 per females) .Statistically done using one way ANOVA followed by Dunnett's tes

## CONCLUSION

The current toxicity study proves that recommended dose of the Siddha drug Oma kudineer, does not produce any pathological symptoms throughout the dosing period of 14 days. So the safety drug dose of Oma kudineer is 2000 mg/kg /body weight

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