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Research Article

ACUTE TOXICITY STUDY OF SIDDHA FORMULATION – GANDHAGA PARPAM

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ABSTRACT

The Siddha system of medicine is one of the oldest systems belongs to southern part of India. This system uses a fascinating combination of herbs, minerals, animal products and special therapy techniques like Varmam, Thokkanam therapy to promote health and longevity. Gandhaga parpam is one of the medicines prepared from Sulphur and other ingredients. To study the acute toxicity studies as per WHO guidelines. The Gandhaga parpam was prepared from raw drugs with authentication. The acute toxicity studies carried out in Albino mice (Male and Female) with 10 times of therapeutic dose i.e. 260 mg/day, water solute, for 2 weeks. Gandhaga parpam at the dose 4.68 mg/animal did not exhibit any mortality in mice. No behavior changes noted for first 4 hours, 24 hours and throughout the study period of 14 days. In addition, no weight reduction happened. Thus, the Siddha formulation of Gandhaga parpam, proves this drug was safe and recommended for human usage. The above result shows that even any metal or mineral medicine should be prepared as per procedure mentioned in classical texts, it does not exhibit any toxicity studies. This will help to reach the Siddha system globally.

Keywords: Toxicity, Siddha formulation, Weight, Behavioral changes.

INTRODUCTION

The word Siddha comes from the word "Siddhi" which means attaining perfection or heaven. Siddha system uses a fascinating combination of herbs, minerals, animal products and special therapy techniques like Varmam, Thokkanam therapy to promote good health and longevity. In India, the Government has recognised the following traditional systems like Siddha system, Ayurveda, Unani, Homeopathy and Naturopathy collected in one umbrella and namely AYUSH systems. The medicines using in the traditional systems validated according to modern scientific parameters for the usage in human beings. The Siddha literature explained the purification process for each raw drug. If we strictly follow the purification process for herbal, metal or mineral drugs, it will improve the bioavailability; enhance the curing principles and less to side effects. Author selected the Gandhaga parpam (Internal drug) for clinical study, which mentioned in Anuboga Vaidhiya Navaneedham Part 6[1]. The drug Gandhagam (Sulphur) is a crystalline material. Therefore, to study the acute toxicity as per WHO Guidelines, 1993 for the prepared drug Gandhaga parpam before going to enter clinical study.

MATERIALS AND METHODS

Gandhaga parpam preparation

Ingredients

- Purified Nellikkaai Gandhagam (sulphur)- 1 Palam (35 gm)
- Ash of the bark of Maruthampattai- 1.5 Azhakku (270 gm) (*Terminalia arjuna.* Roxb.ex. Dcwight and Arn.)
- Lemon Juice- Required amount

Method of purification

Purification of Gandhagam

Sulphur is taken in an iron ladle along with some cow's butter and melted in heat. Then poured into cow's milk and allowed to cool for solid state. This process repeated for 29 times. Sulphur is taken out and dried[2].

Purification of Arjuna bark

Bark cleaned with pure cloth and the outer layer peeled off[3].

Method of preparation

Purified Sulphur soaked in the lime juice for 60 Nazhigai (24 hours). Maruthampattai (*Terminalia arjuna*) bark burnt and made to ash form. Half the quantity of ash of Maruthampattai taken in a narrow-mouthed clay pot and the purified Sulphur placed over this ash. Remaining half of the ash was covered the Sulphur completely. The plaster made up of fine clay applied over the cotton cloth to cover the pot and lid tightly as per siddha literature and dried.

It then subjected to calcination process (Pudam) by placing it in a pit, depth of oru Muzham (46.6 cm approximate). The cow dung cakes of 100 Palams (3500 gm), half-placed below, place the clay

pot and cover above with remaining half of cakes. In addition, start the firing of dung cakes. After completely burnt out of cakes, allowed to cool. Clay pot opened and powdered the Gandhagam. The Gandhaga parpam was prepared and stored in the airtight container[3].

Acute toxicity studies

Test animals

Acute Toxicity study carried out at National Institute of Siddha, Chennai. Test animals (Swiss albino mice) borrowed from the King Institute animal laboratory, Chennai. All the animals kept under standard environmental condition (27+ or – 2-degree Celsius). The animals had free access to water and standard pellet diet (Sai Durga foods pvt. Ltd, Bangalore). The principles of laboratory animal care and study design followed, the Institutional Ethical Committee also approved, and certificate no is NIS/3 1/2011 /10 dated on 27.04.2011.

Route of administration

Oral route, the normal route of clinical administration

Test substance and vehicle

The Gandhaga parpam is light brown in color. The test substance is soluble in water, in order to obtain and ensure the uniformity in drug distribution.

Administration of doses

Gandhaga parpam suspended in water with uniform mixing and administered to the groups in a single oral dose. Equal volume of the vehicle administered to the control groups. The animals weighed before giving the drug. The dose level calculated according to body weight, and surface area. Since the clinical dose was 260 mg\day, converted to animal dose (4.68 mg) and then administered. Proper animal care is given[4-6].

Acute toxicity carried out in Swiss albino mice with a single exposure of 10 times of the recommended therapeutic dose of test compound the study duration will be 14 days[7-11].

- Animal species: Swiss albino mice.
- Age: 6 weeks.
- Weight: Mice-20-25 gm.
- Gender: Both male and female.
- Number of Animals (Control): 10 Mice(5 Male, 5 Female)
- Number of Animals (Toxic dose) : 10 Mice (5 Male, 5 Female)
- Acclimatization Period:7 Days
- Vehicle control: Saline
- Toxic dose: mg (10X therapeutic dose)
- Clinical dose:260 mg\day

Observations

Observations recorded systematically and continuously observed as per the guideline after substance administration. The animals monitored for behavioral parameters like

1. Awareness- Alertness, Visual placing, Stereotype, Passivity
2. Mood - Grooming, Restlessness, Irritability, Fearfulness
3. Motor activity - Reactivity, Spontaneous activity, Pain response, Touch response

For the first four hours after doing administration, body weight of the animal monitored at weekly interval.

During the trial period 14 days, the animals monitored for apparent signs of toxicity. The animals that die within this period may subject to necropsy. All animals weighed and sacrificed on the 15th day after administration and then the vital organs including heart, lungs, livers, kidneys, sex organs and brain grossly examined.

Body weight

Individual weight of animals was determined before the test substance was administered and daily for 14 days. Weight changes were calculated and recorded. At the end of the test, surviving animals weighed and sacrificed.

RESULT AND DISCUSSION

Gandhaga parpam at the dose 4.68 mg/animal did not exhibit any mortality in mice. No behavior changes noted for the first 4 hours and 24 hours and throughout the study period of 14 days. No weight reduction observed during the study period. Acute toxicity of this trail drug shows no toxicity. Even though the sulphur had the property of creating toxicity in human body while consuming, this Trail drug Gandhaga parpam was prepared as per classical Literature procedure like purification, calcination process and grinding is the reason that this medicine safe and didn't exhibit any toxicity. Thus, the Siddha formulation of Gandhaga parpam recommended for human usage.

CONCLUSION

The Gandhaga parpam toxicity study shows that it's safe *in vitro* studies. This result proves that while we prepare the medicine from metal or mineral, if strictly adheres all the procedures as per literatures like purification, grinding, drying, calcination process will help in good results *in vitro* and *in vivo* studies.

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