Dolloh-650 Clinical Trial Results

Sponsor
SuryaPharma

Generic Drug Name
Dolloh-650; Dolloh-650 is a paracetamol tablet containing 650 mg of Acetaminophen.

Trial Indication(s)
To check if Dolloh 650 relieves the patients from pain and fever, and whether it can be use to treat headaches and migraines.

Protocol Number
D650A101

Protocol Title
A 6-week randomized, controlled, multicenter, open-label study to evaluate the effects of Dolloh-650 tablets on patients with moderate injury or moderate migraine.

Clinical Trial Phase
Phase II

Phase of Drug Development
Phase IV

Study Start/End Dates
Study Start Date: 01st May 2024
Study End Date: 14th June 2024

Reason for Termination (If applicable)
Not Applicable

Study Design/Methodology
Study D650A101 was a multicenter, 1:1 randomized, controlled, parallel-group open label study to investigate the effects of Dolloh-650 tablets on subjects with moderate injury or moderate migraine. This study recruited subjects who had an injury or chronic headache 2 weeks prior to first visit.

Centers
3 centres in India; Mumbai, Pune, and Bangalore.

Objectives:
The main objective of this trail is to test the effectiveness of Dolloh-650 tablets and to verify if there are any side-effects from consuming these tablets.

Test Product (Devices), Dose(s), and Mode(s) of Administration
Across all three centres, a total number of 20 subjects participated in this trail. All of them were given one tablet of Dolloh-650 once every week. Their blood pressure and other vitals were constantly checked for 3 hours after the dosage.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria

1. Male and female; 18 years or older
2. Moderate migraine patients
3. Chronic injury patients

Exclusion criteria

1. High blood pressure patients
2. Disabled patients
3. Male and female; below 18 years

Subject Flow Table

Subject Diposition	**Subjects**
Started	20
Completed	20
Incompleted	0

Baseline Characteristics

Demographics	**Subjects**
18 to 35 years	10
35 to 60 years	10
Male	10
Female	10

Safety Results

Frequency Threshold for Reporting Other Adverse Events: 0%

Subjects with frequent Adverse Events (AEs) by system organ class (Enrolled Population): 0%

Subjects with frequent AEs by preferred term (Enrolled Population): 0%

Serious Adverse Events (SAEs) and Deaths: 0%

Conclusion:

All of the test subjects showed improvement in their health. No side-effects occured to the test subjects.

Date of Clinical Trial Report:

16th July 2024