Clinical Trial Details (PDF Generation Date :- Fri, 05 Jan 2024 07:32:56 GMT)

CTRI Number	CTRI/2022/04/042212 [Registered on: 27/04/2022] - **Trial Registered Prospectively**
Last Modified On	06/10/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Single Arm Study
Public Title of Study	Zero Tension Tablet for mild to moderate stress, anxiety and insomnia disorder Study
Scientific Title of Study	An open label, multicentric, prospective, non-randomized, phase-IV post-marketing, surveillance study to evaluate the efficacy and safety of "Zero Tension Tablet" in individuals suffering from mild to moderate stress, anxiety and insomnia disorders

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Sushma BH
Designation	MBBS, MD in psychiatry
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Vijay Kimtata
Designation	Scientific Research Person
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
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Designation	Director
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Alna Biotech Pvt. Ltd Plot No. 21,HSIIDC, Industrial Estate, Alipur (Barwala), Panchkula (HR) 134118

Primary Sponsor

Primary Sponsor Details	
Name	ALNA BIOTECH PVTLTD
Address	Plot No. 21,HSIIDC, Industrial Estate, Alipur (Barwala), Panchkula (HR) 134118
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Sushma BH	Campbell Hospital	No.11/A, HSR Layout, Sector-6, Outer Ring Road, Bangalore-560102. Bangalore KARNATAKA	91-9986096863 dr.sushmabh@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
ACE Independent Ethics Committee	Approved	20/04/2022	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders
Patients	Mental, Behavioral and Neurodevelopmental disorders
Patients	Nonpsychotic mental disorder, unspecified
Patients	Other nonpsychotic mental disorders

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1. Adults in the age of 18-60 years. 2. Subjects with general good health as determined by the investigator. 3. Individuals presenting with mild to moderate stress, anxiety and insomnia disorders and further fulfilling one or both of the following criteria: a. Score of 17-24 on the Hamilton-A Scale b. A score 14-26 on the Perceived Stress Scale (PSS)

Exclusion Criteria

Exclusion Criteria	
Details	1. Individuals who have taken prior medication for stress or anxiety in the last three months.

	2. Individuals with comorbid conditions such as thyroid disorders, uncontrolled hypertension and uncontrolled diabetes mellitus. 3. Individuals with mental disorder such as Schizophrenia, Alzheimer's disease etc, except anxiety and insomnia. 4. Individuals with significant and uncontrolled acute or chronic coexisting illness related to cardiovascular, respiratory, gastrointestinal, immunological, metabolic, endocrinology, neurological system or any other condition which in the investigator's judgement contraindicate entry into the study. 5. History of taking (within 4 weeks prior to screening) psychoactive medication (anxiolytics, sedatives, hypnotics, anti-psychotics, anti-depressants, anticonvulsant, centrally acting corticosteroids, opioid pain relievers) hypnotics, narcotic analgesics, antidepressants, anticonvulsants, sedating H1 antihistamines, over-the-counter and prescriptions stimulants, decongestants, melatonin, drugs for oral alkalization, and all other drugs or supplements known to affect sleep cycle. 6. A known history or present condition of allergies that may require medical attention. 7. History or present case of alcohol or drug dependence (illicit drug users) 8. Present case of smoking and self-declared illicit drug users (including cannabis and cocaine) 9. Individuals suffering from PCOS or PCOD. 10. Subjects not willing to stop the use of another product similar to the test product during study period. 11. Subjects who are pregnant or are planning to get pregnant during the course of the study.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
To compare efficacy of "Zero tension" as compared to baseline for improvement in the signs and symptoms of anxiety, stress and insomnia disorders.	Day 1-Day 56

Secondary Outcome

Outcome	Timepoints
Improving general wellbeing, safety and compliance of the study drug.	Day 1-Day 56

Target Sample Size	**Total Sample Size=**100 **Sample Size from India=**100 **Final Enrollment numbers achieved (Total)=**100 **Final Enrollment numbers achieved (India)=**100
Phase of Trial	Phase 4
Date of First Enrollment (India)	10/05/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of	Not Applicable

Trial (Global)	
Recruitment Status of Trial (India)	Completed
Publication Details	Nil
Brief Summary	The study is an Open label, Multicentric, Prospective, Non- randomized, Phase IV, Post-marketing surveillance study on 100 adult subjects. There are 4 visits in the study with one being telephonic follow-up. On screening visit i.e, Day 0, the subjects will be screened based on inclusion and exclusion criteria. An informed consent form will be given to all subjects at the screening visit containing all study information in it. Eligible subjects will be enrolled into the study after the informed consent procedure and laboratory investigations report. Blood will be drawn from the subjects for laboratory investigations (CBC, RBS, TFT, SGPT and Serum Creatinine) on Day 0 and Day 56. Investigator will explain the subject about all study-related procedures, the telephonic follow-up on Day 28 (Visit 3) and end of study on Day 56 (Visit 4). All eligible subjects will be then provided with IP- Zero Tension Tablet by investigator/ study coordinator on Day 1 (Visit 2). Instructions will be given to the subjects to use the IP at home from Day 1 to Day 56 i.e, 2 tablets before going to bed. An Investigator's Assessment Questionnaire will be assessed on Day 0 and Day 56 whereas, Subjective Assessment Questionnaire will be performed on Day 0, day 28 and Day 56 to evaluate the efficacy of IP- Zero Tension Tablet.