TCTR Search WHO ICTRP Search

Example : asthma AND corticosteroid

asthma Search Manual Advanced Search

Keyword: **kenra**
Filter (Sandbox : **All** | Study Type: **All** | Study Result: **All**) Plan to share data: **All** |
1 records found

TCTR ID : TCTR20130320009
OTHER ID :

Overall Recruitment Status : *Completed (Has Results)*
Retrospective registration
This protocol was registered after enrollment of the first participant.

First Submitted Date : 19 March 2013
First Posted Date : 20 March 2013
Last Update Posted Date : 19 March 2013

PDF XML

Public Title

Public Title : *
Study on the Safety of Kenra Formula Capsule by Oral Administration on Healthy Volunteers
Acronym : NHS
Scientific Title : *
Study on the Safety of Kenra Formula Capsule by Oral Administration on Healthy Volunteers
Sponsor ID/ IRB ID/ EC ID : *
WUEC-22-293-01
Registration Site : *
Thai Clinical Trials Registry
URL : *
https://www.thaiclinicaltrials.org/show/TCTR20130320009
Secondary ID : *
No Secondary ID

Ethics Review

1.Board Approved : *
Submitted, approved
Approval Number : *
WUEC-22-302-01
Date of Approval : *
11 October 2022
Board Name : *
Ethics Committee in Human Research Walailak University
Board Affiliation : *
Walailak University, Thailand

Board Contact : *
Business Phone : *
075673590 Extension :
1
Business Email : *
Wu.khuan@Gmail.Com
Business Address : *
222 Walailak University, Thai Buri, Tha Sala, Thailand, 80160

Sponsor

Source(s) of Monetary or Material Supports : *
EASTERN HERB COMPANY LIMITED
Study Primary Sponsor : *
EASTERN HERB COMPANY LIMITED

Responsible Party :
Name/Official Title : *
EASTERN HERB COMPANY LIMITED
Organizational : *
EASTERN HERB COMPANY LIMITED
Phone : *
0992458080 Extension :
Business Email : *
jnangsue@gmail.com

Study Secondary Sponsor : *
1. Walailak University

Protocol Synopsis

Protocol Synopsis :
We will investigate the effects and safety of using Kenra formula herbs on the functioning of the liver, kidneys, and blood system, as well as potential adverse reactions of herbal formulations in healthy volunteers.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : *
healthy volunteers
Keywords : *
phase I clinical trial, safety, Kenra Formula Capsules

Eligibility

Inclusion Criteria : *
1. Healthy volunteers, 2. Participants with no history of congenital diseases, as determined through a medical history and physical examination, 3. Participants who do not smoke or drink alcohol regularly, and are not addicted to drugs, 4. Participants who do not regularly take any medications, supplements, or health products, 5. Participants with no history of infection with Coronavirus-2019, 6. Participants who provided consent to participate in the project

Gender : *
Both
Age Limit : *
Minimum : 20 Years Maximum : 35 Years

Exclusion Criteria : *
1. Participants who are unable to provide blood samples, 2. Individuals with a history of drug, herb, or food allergies, 3. Female volunteers who are pregnant or have the potential to become pregnant, 4. Participants who are infected with COVID-19, 5. Individuals with abnormal laboratory results indicating impaired liver or kidney function, abnormal coagulation values, or abnormal blood sugar levels

Accept Healthy Volunteers? : *
Yes

Status

Overall Recruitment Status : *
Completed

Key Trial Dates

Study Start Date (First enrollment) : *
03 November 2022
Indicate Type : *
Actual

Completion Date (Last subject, Last visit) : *
13 December 2022
Indicate Type : *
Actual

Study Completion Date : *
14 December 2022
Indicate Type : *
Actual

Design

Study Type : *
Interventional
Primary Purpose : *
Other
Study Phase : *
Phase 1
Intervention Model : *
Single arm
Number of Arms : *
1
Masking : *
Open Label
Allocation : *
N/A
Control : *
N/A
Study Endpoint Classification :
Safety Study
I : *

Sample Size : **Planned sample size** : * 14 **Actual sample size at study completion** : * 11

Intervention Arms : *
Arm 1
Intervention Name : *
Kenra Formula Capsule: traditional medicine (number G46/57)
Intervention Type : *
Experimental
Intervention Classification : *
Drug
Intervention Description : *
The volunteers orally received two capsules (500 mg/cap) four times per day, three times before meals and once before bedtime, for 14 days.

Outcome

Primary Outcome

1. Outcome Name : *
Normal blood analysis
Metric / Method of measurement : *
CBC
Time point : *
1, 7, 14 days 14 days after the washout period

2. Outcome Name : *
Coagulogram
Metric / Method of measurement : *
PT and APTT
Time point : *
1, 7, 14 days 14 days after the washout period

3. Outcome Name : *
Renal function
Metric / Method of measurement : *
AST, ALT, ALP
Time point : *
1, 7, 14 days 14 days after the washout period

4. Outcome Name : *
Kidney function
Metric / Method of measurement : *
BUN, Creatine, Urinalysis
Time point : *
1, 7, 14 days, 14 days after the washout period

5. Outcome Name : *
Inflammation
Metric / Method of measurement : *
ESR, CRP
Time point : *
1, 7, 14 days, 14 days after the washout period

6. Outcome Name : *
Glucose level
Metric / Method of measurement : *
FBS
Time point : *
1, 7, 14 days, 14 days after the washout period

7. Outcome Name : *
Lipid profiles
Metric / Method of measurement : *
Cholesterol, Triglyceride, HDL, LDL
Time point : *
1, 7, 14 days, 14 days after the washout period

Secondary Outcome

1. Outcome Name : *
Adverse effect
Metric / Method of measurement : *
Physical examination
Time point : *
1, 7, 14 days, 14 days after the washout period

Location

Section A: Central Contact

Central Contact:
First : * Suriyan **Middle** : **Last** : * Sukati **Degree** : MT, PhD
Phone : * 0846474678 **Ext.** : **Email** : * suriyan.su@wu.ac.th

Central Contact Backup:
First : * Chaiwat **Middle** : **Last** : * Kerkswatsaxon **Degree** : MD
Phone : * 075672873 **Ext.** : **Email** : * chaiwat.ke@wu.ac.th

Section B: Facility Information and Contact

1. Site Name: Walailak University
City The Sala **State/Province** : * Nakhon Si Thammarat **Postal Code** : * 80160
Country : * Thailand **Recruitment Status** : Completed

Facility Contact
First : * Suriyan **Middle** : **Last** : * Sukati **Degree** : MT, PhD
Phone : * 0846474678 **Ext.** : **Email** : * suriyan.su@wu.ac.th

Facility Contact Backup
First : * Chaiwat **Middle** : **Last** : * Kerkswatsaxon **Degree** : MD
Phone : * 075672873 **Ext.** : **Email** : * chaiwat.ke@wu.ac.th

Investigator Name
First : * Suriyan **Middle** : **Last** : * Sukati **Degree** : MT, PhD
Role : * Principal Investigator

Section C: Contact for Public Queries (Responsible Person)

Contact for public Query's Name
First : * Suriyan **Middle** : **Last** : * Sukati **Degree** :
Postal Address : * 222 Walailak University, Thai Buri, Tha Sala
State/Province : * Nakhon Si Thammarat **Postal Code** : * 80160
Country : * Thailand
Official Role : * Study Principal Investigator
Organization Affiliation : * Walailak University

Section D: Contact for Scientific Queries (Responsible Person)

Contact for Scientific Query's Name
First : * Suriyan **Middle** : **Last** : * Sukati **Degree** : MT, PhD
Postal Address : * 222 Walailak University, Thai Buri, Tha Sala
State/Province : * Nakhon Si Thammarat **Postal Code** : * 80160
Country : * Thailand
Official Role : * Study Principal Investigator
Organization Affiliation : * Walailak University

Summary Results

Date of posting of results summaries : *
19 March 2023
Date of first journal publication of results :
Not yet published
Baseline Characteristics : *
The physical examination includes measurement of height, weight, calculation of body mass index (BMI), measurement of body temperature, pulse, blood oxygen saturation, blood pressure, and a general characteristics examination. Additionally, examination of the head, neck, ears, nose, heart, lungs, abdomen, and nervous system are conducted. Laboratory investigations are also carried out, including CBC (complete blood count), PT (prothrombin time), APTT (activated partial thromboplastin time), AST (aspartate aminotransferase), ALT (alanine aminotransferase), ALP (alkaline phosphatase), FBS (fasting blood sugar), lipid profiles, BUN (blood urea nitrogen), Creatine, CRP (C-reactive protein), ESR (erythrocyte sedimentation rate), and urinalysis. Base line are normal ranges: Systolic blood pressure (mmHg): 120.45, Diastolic blood pressure (mmHg): 73.55, BMI (kg/m2): 22.01, Hemoglobin (g/dl): 13.90, RBC count (cells/microliter): 4,840,000, WBC count(cells/microliter): 6,520, Platelet (cells/microliter): 271,000, AST (U/L): 28.0, ALT (U/L):14.44, ALP (U/L): 65.16, BUN (mg/dL): 10.26, Creatinine (mg/dL): 0.86, Cholesterol (mg/dl): 195.73, Triglyceride (mg/dl): 87.73, HDC (mg/dl): 65.73, LDL: 124.00, FBS (mg/dL): 88.44, ESR (mm/hr): 5, CRP (mg/dL): less than 0.6, Normal urinalysis
Participant Flow : *
A total of 24 volunteers, consisting of 11 males and 13 females, participated in the health assessment through history taking, physical examination, and laboratory examination by a doctor. Among them, 19 volunteers were healthy, with 10 females and 9 males. Fourteen healthy volunteers, consisting of 7 males and 7 females, were randomly assigned to take Kenra capsules. During the study, three subjects were withdrawn, with one subject withdrawing their consent to participate and one taking paracetamol. Additionally, one person was infected with Coronavirus 2019. Therefore, the data collected from the eleven healthy subjects who completed the study and provided research data, consisting of 6 females and 5 males, with a mean age of 20-23 years, was considered complete.
Adverse events : *
No abnormal laboratory findings and all various adverse events.
Outcome Measures : *
There were no significant differences in laboratory results observed after taking the herb capsule for 1, 7, and 14 days, as well as after the 14-day washout period. Furthermore, no adverse effects were observed during the physical examination and follow-up of the volunteers after taking the herbs.
Brief Summary of Results : *
This study indicates that taking herbal capsules of the Kenra formulation for 14 consecutive days at a total dose of 4,000 mg per day (1,000 mg four times per day) is safe. However, further studies are warranted to evaluate the long-term effects of the herbs.

Deidentified Individual Participants-level Data Sharing

Plan to share IPD : *
Yes
Plan Description : *
IPD and documents will be available for sharing 1 year after publication for a period of 2 years.

Publication from this study

MEDLINE Identifier
URL link to full text publication