TCTR ID : TCTR20210201005

OTHER ID :

Overall Recruitment Status : Completed **(No Results)**

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date :	01 February 2021
First Posted Date :	01 February 2021
Last Update Posted Date :	29 May 2023

Title

Public Title :	Safety and pharmacokinetic studies of Andrographis paniculata extracts in Thai healthy volunteers
Acronym :	No Data
Scientific Title :	Safety and pharmacokinetic studies of Andrographis paniculata extracts in Thai healthy volunteers
Sponsor ID/ IRB ID/ EC ID :	062/2563
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20210201005
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	062/2563
Date of Approval :	28 August 2020
Board Name :	Human Research Ethics Committee
Board Affiliation :	chulabhorn royal academy
Board Contact :	Business Phone : 025766000 Ext. 8431
	Business Email : ethics.ccc@gmail.com
	Business Address : 906 Kamphaeng Phet 6 Rd., Talat Bang Khen, Lak Si, Bangkok 10210, Thailand

Sponsor

Source(s) of Monetary or Material Supports :	Chulabhorn Research Institute
Study Primary Sponsor :	Thailand Science Research and Innovation (TSRI)
Responsible Party :	Name/Official Title : Porranee Puranajoti
	Organization : International Bio Service, Mahidol University
	Phone : 024415211 Ext. 220
	Email : porranee.pur@mahidol.ac.th
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	(Objectives) To investigate safety and pharmacokinetics of Andrographis paniculata extract including metabolite profiles in blood and urine. (Study design) This study is a phase I, single and multiple oral dosing in Thai healthy volunteers, who each received the Andrographis paniculata extract (capsules A or B) at 180 mg/day or 360 mg/day, first as a single dose and then a week later for 7 consecutive days under a fasting condition.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Healthy volunteers with normal physical examination and vital signs Screening visit laboratory of the blood test are within the normal range.
Keywords :	Healthy volunteers Safety Pharmacokinetics

Eligibility

Inclusion Criteria :	1. Subjects who are Thai male or female, aged 18 to 55 years (inclusive). 2. Subjects whose BMI is 18 30 kg/m2 (inclusive). 3. Subjects who are negative result of COVID 19 test.

4. Subjects who are healthy by medical history, physical examination, 12 lead ECG, and vital signs.
5. whose screening visit laboratory values of blood tests including complete blood count, hematocrit, glucose, blood urea nitrogen, serum creatinine, alkaline phosphatase, ALT, AST, total bilirubin, albumin, total cholesterol, triglycerides, HDL cholesterol, electrolytes, Hepatitis Bs antigen and anti HIV are within the normal range or showing no clinically significant abnormalities as confirmed by the clinical investigator.
6. For female subjects:
6.1 Female subject who is in childbearing potential must have urine pregnancy test negative and agrees to use an acceptable birth control method from visit 1 to the last visit. The acceptable birth control method is defined as a barrier method of contraception (including condoms, intrauterine device (IUD) and diaphragm with spermicial agent) or total abstinence from sexual intercourse from visit 1 to the last visit. Hormonal contraceptives are not acceptable.
6.2 Female subject who is in child bearing potential must agree not to become pregnant for the entire participation phase and must have a negative result for urine pregnancy test performing prior to dosing
6.3 Female subjects can be those with non childbearing potential which defined as female subjects with hysterectomy, both ovaries removed, surgically sterilized or postmenopausal (for at least 12 consecutive months of amenorrhea).
7. Subjects are able to understand the requirements of the study and voluntarily sign and date an informed consent, approved by the Independent Ethic Committee (IEC)/ Institutional Review Board (IRB), prior to the initiation of any screening or study specific procedures.

Gender : Both

Age Limit : Minimum : 18 Years Maximum : 55 Years

Exclusion Criteria : 1. Subjects who are with a history of COVID 19 positive test.
2. Subjects who are with a history/evidence of allergy or hypersensitivity to Andrographis paniculata.
3. Subjects who have a history of any illness that, in the opinion of the clinical investigator, might confound the result of the study or pose an additional risk in administrating AP capsule to the subjects. This may include but not limited to: a history of relevant drug or food allergies; history or cardiovascular, gastrointestinal, central nervous system disease, renal and hepatic impairment; history or presence of clinically significant illness; or history of mental illness that may affect compliance with study requirements.
4. Subjects who are with a history of heavy smoking (more than 10 cigarettes per day) or moderate smoking (less than 10 cigarettes per day) and cannot omit smoking at least one day before the study and until the completion of the study phase.
5. Subjects who are with a history of alcoholic (more than 2 years) or moderate drinkers (more than 3 drinks per day one is equal to one unit of alcohol: one glass of wine, half pine of beer or one measure of spirit) or subjects who are with a history of any drug abuse.
6. Subjects who receive of any medical prescription within 14 days [especially any drug related to enzyme CYP450 inducer or inhibitor: CYP1A2 (theophylline)] before the first administration of AP capsule.
7. Female subjects who are pregnant or breast feeding.
8. Subjects who are participating in any investigational drug study or had been in any investigational drug study within 3 months prior to the screening visit.

Accept Healthy Volunteers : Yes

Status

Overall Recruitment Status : Completed

Key Trial Dates	Study Start Date (First enrollment) : 01 November 2021	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 28 February 2022	Indicate Type : Actual
	Study Completion Date : 30 April 2022	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Other

Study Phase : Phase 1

Intervention Model : Parallel

Number of Arms : 4

Masking : Masked Masked Role : Allocation concealment, Subject, Caregiver, Investigator, Outcome Assessor, Statistician

Allocation : Non-randomized

Control : Dose Comparison

Study Endpoint Classification : Pharmacokinetics Study

Sample size

Planned sample size : 48

Actual sample size at study completion :

Intervantion Arm 1

Intervention name : capsule A: 180 mg/day

Intervention Type : Experimental

Intervention Classification : Other

Intervention Description : Single and multiple oral administration of Capsule A, Dose: AP1 equivalent to 180 mg/day (60 mg x 3 times/day, every 8 hr) duration: 1 and 1-7 days

Intervantion Arm 2

Intervention name : capsule B: 180 mg/day

Intervention Type : Experimental

Intervention Classification : Other

Intervention Description : Single and multiple oral administration of Capsule B, Dose: AP1 equivalent to 180 mg/day (60 mg x 3 times/day, every 8 hr) duration: 1 and 1-7 days

Intervantion Arm 3

Intervention name : capsule A: 360 mg/day

Intervention Type : Experimental

Intervention Classification : Other

Intervention Description : Single and multiple oral administration of Capsule A, Dose: AP1 equivalent to 360 mg/day (120 mg x 3 times/day, every 8 hr) duration: 1 and 1-7 days

Intervantion Arm 4

Intervention name : capsule B: 360 mg/day

Intervention Type : Experimental

Intervention Classification : Other

Intervention Description : Single and multiple oral administration of Capsule B, Dose: AP1 equivalent to 360 mg/day (120 mg x 3 times/day, every 8 hr) duration: 1 and 1-7 days

Outcome

Primary Outcome

1. Outcome Name : Pharmacokinetic parameters

Metric / Method of measurement : Non compartmental analysis will be applied to determine pharmacokinetic parameters and performed by PK solutions software (version 2.0)

Time point : 0, 0.167, 0.333, 0.5, 0.75, 1, 1.5, 2, 4, 6, 8, 10, 12 and 24 hr

Secondary Outcome

1. Outcome Name : safety profiles

Metric / Method of measurement : The descriptive data will be used to describe demographic characteristics and to summarize the continuous variables. Data processing will be performed using STATA software or SPSS

Time point : Day(0-4) and Day 7

Location

Section A : Central Contact

Central Contact	First Name : Phanit	Middle Name :	Last Name : Songvut
	Degree : Ph.D	Phone : 025538555 Ext. : 8292	Email : phanit@cri.or.th
Central Contact Backup	First Name : Jutamaad	Middle Name :	Lastname : Satayavivad
	Degree : Ph.D	Phone : 025538555 Ext. : 8539	Email : jutamaad@cri.or.th

Section B Facility Information and Contact

1. Site Name : international bio service

	City : Salaya	State/Province : Nakhon Pathom	Postal Code : 73170
	Country : Thailand	Recruitment Status : Pending (Not yet recruiting)	
Facility Contact	First Name : Porranee	Middle Name :	Last Name : Puranajoti
	Degree : Ph.D	Phone : 025538555 Ext. : No Data	Email : porranee@cri.or.th
Facility Contact Backup	First Name : Jutamaad	Middle Name :	Last Name : Satayavivad
	Degree : Ph.D	Phone : 025538555 Ext. : No Data	Email : jutamaad@cri.or.th
Investigator Name	First Name : Jutamaad	Middle Name :	Last Name : Satayavivad

Degree : Ph.D | Role : Principal Investigator

Section C : Contact for Public Queries (Responsible Person)

First Name : Jutamaad | Middle Name : | Last Name : Satayavivad
Degree : Ph.D | Phone : 025538555 Ext. : No Data | Email : jutamaad@cri.or.th
Postal Address : 54 Kamphangphet 6, Laksi
State/Province : Bangkok | Postal Code : 10210
Country : Thailand | Official Role : Study Principal Investigator
Organization Affiliation : Chulabhorn Research Institute

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Jutamaad | Middle Name : | Last Name : Satayavivad
Degree : Ph.D | Phone : 025538555 Ext. : No Data | Email : jutamaad@cri.or.th
Postal Address : 54 Kamphangphet 6, Laksi
State/Province : Bangkok | Postal Code : 10210
Country : Thailand | Official Role : Study Principal Investigator
Organization Affiliation : Chulabhorn Research Institute

Summary Results

Date of posting of results summaries : Summary results not yet available
Date of first journal publication of results : Not yet published

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No
Reason : Need a consensus from colleagues

Publication from this study

MEDLINE Identifier : No Data
URL link to full text publication : No Data