

**TCTR ID : TCTR20230719003**

Overall Recruitment Status : Completed (Has Results)

**OTHER ID :**

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

---

**Tracking Information**

First Submitted Date : 18 July 2023  
First Posted Date : 19 July 2023  
Last Update Posted Date : 15 October 2024

---

**Title**

Public Title : Bioequivalence study of empagliflozin 25 mg film-coated tablet in Thai healthy volunteers  
Acronym : BE01-2023  
Scientific Title : Bioequivalence study of empagliflozin 25 mg film-coated tablet in Thai healthy volunteers  
Sponsor ID/ IRB ID/ EC ID : BE01-2023  
Registration Site : Thai Clinical Trials Registry  
URL : <https://www.thaiclinicaltrials.org/show/TCTR20230719003>  
Secondary ID : No Secondary ID

---

**Ethics Review**

1. Board Approval : Submitted, pending  
Board Name : Institutional Review Board  
Board Affiliation : Faculty of Medicine, Chulalongkorn University  
Board Contact : Business Phone : 022564493 Ext. No Data  
Business Email : medchulairb@chula.ac.th  
Business Address : Faculty of Medicine, Chulalongkorn University, Anantamahidol Building, 3rd floor, Henri Dunant Road, Pathumwan, Bangkok 10330

---

**Sponsor**

Source(s) of Monetary or Material Supports : Macrofar Co., Ltd.  
Study Primary Sponsor : Macrofar Co., Ltd.  
Responsible Party : Name/Official Title : Ms. Lumduan Polpanich  
Organization : Macrofar Co., Ltd.  
Phone : 023146671 Ext. No Data  
Email : ing@macrofar.co.th  
Study Secondary Sponsor : No Study Secondary Sponsor

---

**Protocol Synopsis**

Protocol Synopsis : a randomized, an open-labeled, two-treatment, two-period, two-sequence, single dose crossover Bioequivalence Study of Empagliflozin 25 mg Film-coated Tablets (Empazin 25 mg) and Reference Product (Jardiance 25 mg) in HealthyThai Volunteers under fasting condition

---

**URL not available**

---

**Health Conditions**

Health Condition(s) or Problem(s) Studied : Healthy Thai Volunteers  
Keywords : Healthy Thai Volunteers

---

**Eligibility**

Inclusion Criteria : Healthy Thai Volunteers  
Gender : Both  
Age Limit : Minimum : 18 Years Maximum : 55 Years  
Exclusion Criteria : Subjects who are with a history/evidence of drug sensitivity or allergic reaction to empagliflozin, or any related drug. Subjects who are positive for COVID-19 test.  
Accept Healthy Volunteers : Yes



**Section B Facility Information and Contact**

1. Site Name : Chula Pharmacokinetic Research Center

City : Pathumwan State/Province : Bangkok Postal Code : 10330

Country : Thailand Recruitment Status : Pending (Not yet recruiting)

**Facility Contact** First Name : Ms. Nantaporn Middle Name : Last Name : Prompila

Degree : Phone : 0632355951 Ext. : No Data Email : nantaporn.p@chula.ac.th

**Facility Contact Backup** First Name : Assistant Professor Middle Name : Last Name : Chariyavilaskul

Pajaree Degree : Phone : 0816134664 Ext. : No Data Email : pajaree.1@chula.ac.th

**Investigator Name** First Name : Assistant Professor Middle Name : Last Name : Chariyavilaskul

Pajaree Degree : Role : Principal Investigator

**Section C : Contact for Public Queries (Responsible Person)**

First Name : Ms. Nantaporn Middle Name : Last Name : Prompila

Degree : No Data Phone : 0632355951 Ext. : No Data Email : nantaporn.p@chula.ac.th

Postal Address : Faculty of Medicine, Chulalongkorn University, Anantamahidol Building, 3rd floor, Henri Dunant Road, Pathumwan

State/Province : Bangkok Postal Code : 10330

Country : Thailand Official Role : Study Principal Investigator

Organization Affiliation : Faculty of Medicine, Chulalongkorn University

**Section D : Contact for Scientific Queries (Responsible Person)**

First Name : Ms. Nantaporn Middle Name : Last Name : Prompila

Degree : No Data Phone : 0632355951 Ext. : No Data Email : nantaporn.p@chula.ac.th

Postal Address : Faculty of Medicine, Chulalongkorn University, Anantamahidol Building, 3rd floor, Henri Dunant Road, Pathumwan

State/Province : Bangkok Postal Code : 10330

Country : Thailand Official Role : Study Principal Investigator

Organization Affiliation : Faculty of Medicine, Chulalongkorn University

---

**Summary Results**

Date of posting of results summaries : 15 October 2024

Date of first journal publication of results : Not yet published

Baseline Characteristics : 28 Thai healthy subjects (14 males and 14 females) were enrolled in the study.

Participant Flow : 27 subjects were completed for both period 1 and period 2.

Adverse events : Asymptomatic Hypoglycemia (mild level)

Outcome Measures : Cmax, AUC0-t and AUC0-inf which was definitely evidenced by 90% confidence interval are within acceptance range of 80 125%.

Brief Summary of Results : The test product (Empazin 25 mg) and the reference product (Jardiance 25 mg) are bioequivalent.

---

**Deidentified Individual Participant-level Data Sharing**

Plan to share IPD : No

Reason : Personal reasons

---

**Publication from this study**

MEDLINE Identifier : No Data

URL link to full text publication : No Data