# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Bioequivalence study of the Bupropion Hydrochloride prolonged-release 150 mg tablet manufactured by Raha Pharmaceutical Company vs. Zyban ® tablet manufactured by GlaxoSmithKline Pharmaceutical Company in healthy volunteers

## Protocol summary

**Study aim**
Examining the bioequivalency of the Bupropion Hydrochloride prolonged-release tablet formulations with the brand-name ®Zyban

**Design**
A single-dose, not blinded, randomized, bioequivalence clinical trial on 24 healthy volunteers.

**Settings and conduct**
Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. The number of 24 volunteers in the age range of 18-50 years and the Body Mass Index range of 18-30 are voluntarily selected through public notification. One capsule is taken fasting, and blood is taken at 15-times points. Two week later, the process is repeated for the brand medicine

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: the weight range of 60-100 kg; being a non-smoker; being healthy in terms of physical examination, ECG, and the laboratory tests; and Volunteers who have agreed to an informed consent form. Exclusion criteria: History of allergic or adverse reaction to Bupropion or any similar product; blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg; Individuals who have donated whole blood during the previous 2 months of the study or donated bloood

**Intervention groups**
Intervention group 1: the Bupropion Hydrochloride prolonged-release 150 mg tablet manufactured by Raha Pharmaceutical Company is the test product. Intervention group 2:Zyban ® tablet manufactured by GlaxoSmithKline Pharmaceutical Company. In each period, 12 of 24 subjects will be given single dose of this product and for up to 72 hours, 3 ml of blood will be collected from the volunteer at 15 time points each time. After the two-weeks washout period, the volunteers are placed in the opposite group

**Main outcome variables**
Plasma concentration of the drug

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20130313012810N119**
Registration date: **2026-07-31, 1405/05/09**
Registration timing: **prospective**

Last update: **2026-07-31, 1405/05/09**
Update count: **0**

**Registration date**
2026-07-31, 1405/05/09

**Registrant information**

**Name**
Hamed Hamishehkar

**Name of organization / entity**
Drug Applied Research Center, Tabriz University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 41 1336 3311

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-08-01, 1405/05/10

**Expected recruitment end date**
2026-08-03, 1405/05/12
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Bioequivalence study of the Bupropion Hydrochloride prolonged-release 150 mg tablet manufactured by Raha Pharmaceutical Company vs. Zyban ® tablet manufactured by GlaxoSmithKline Pharmaceutical Company in healthy volunteers

**Public title**
Bupropion Hydrochloride tablet bioequivalence
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw
**Exclusion criteria:**
History of allergic or adverse reaction to Indapamide or any similar product Volunteers with blood pressure less than 90/60mm Hg or higher than 140/90mm Hg Individuals who have donated whole blood during the last 2 months Individuals who have donated blood components, such as platelets, within the past 2 weeks
**Age**
From **18 years** old to **55 years** old
**Gender**
Both

**Phase**
Bioequivalence
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **24**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of the both groups will change for the second period
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Crossover
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Tabriz University of Medical Sciences
**Street address**
Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5165665811
**Approval date**
2025-09-08, 1404/06/17
**Ethics committee reference number**
IR.TBZMED.REC.1404.398

## Health conditions studied

### 1

**Description of health condition studied**
Bioequivalence study in healthy volunteers
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Plasma concentration of the drug
**Timepoint**
15 time points at time zero and 1, 2, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24, 48 and 72 hours after drug administration
**Method of measurement**
Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group1: In this group, volunteers are given a single oral dose of the Bupropion Hydrochloride prolonged-release 150 mg tablet manufactured by Raha Pharmaceutical Company. In each period, 12 of 24 subjects will be given single oral dose of this product. After two weeks washout period, the volunteers are placed in the Intervention group 2.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 2: In this group, volunteers are given a single oral dose of the Bupropion Hydrochloride prolonged-release 150 mg tablet manufactured by GlaxoSmithKline Company. In each period, 12 of 24 subjects will be given a single oral dose of this product. After two weeks washout period, the volunteers are placed in the Intervention group 1.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Drug Applied Research Center, Tabriz University of Medical Sciences
**Full name of responsible person**
Hamed Hamishehkar
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Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Raha Pharmaceutical Company
**Full name of responsible person**
Akram Sharifian
**Street address**
Unit 11, Sofeh Industrial Town, km 7 of Shiraz Road, Isfahan
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81791 35148
**Phone**
+98 31 3654 0659
**Email**
int@rahapharm.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Raha Pharmaceutical Company
**Proportion provided by this source**
100
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Industry

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
Hamed Hamishehkar
**Position**
professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available