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Study on the safety and efficacy of Aurantii Fructus Immaturus flavonoid extract tablets (Aolanti) in the treatment of functional dyspepsia

Submission date
24/02/2025

Recruitment status
No longer recruiting

Registration date
09/03/2025

Overall study status
Completed

Last Edited
07/03/2025

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the safety and efficacy of Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) in treating functional dyspepsia (FD) characterized by liver-stomach disharmony, spleen-stomach damp-heat, and food stagnation syndromes. The multicenter clinical trial will explore the therapeutic effects of the drug on FD and provide a foundation for subsequent Phase III clinical trials. This study expects to provide valuable insights into the efficacy and safety of Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) for FD, supporting its potential as a therapeutic option for patients with specific TCM syndromes.

Who can participate?
Adult participants between the ages of 18 and 65 years old meeting the Western diagnostic criteria for FD and the Traditional Chinese Medicine (TCM) syndrome differentiation criteria were enrolled.

What does the study involve?
Patients will be randomly assigned to either the treatment group, receiving Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti), or the control group, receiving a placebo. The treatment group received 4 tablets of Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) three times daily, while the control group received 4 placebo tablets under the same regimen, for a total of 4 weeks. The primary efficacy endpoint was the clinical efficacy based on the Western symptom score for FD, while secondary endpoints included clinical efficacy based on TCM syndrome scores and gastric emptying function assessed by the barium strip method.

What are the possible benefits and risks of participating?
Potential benefits included the alleviation of FD symptoms, particularly for patients with liver-stomach disharmony, spleen-stomach damp-heat, and food stagnation syndromes. Potential

risks involved possible adverse drug reactions, although the study results indicated that Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) were well-tolerated with a favorable safety profile.

Where is the study run from?
The study was conducted across multiple centers in China, including West China Hospital of Sichuan University, Affiliated Hospital of Chengdu University of Traditional Chinese Medicine, The First Affiliated Hospital of Hunan University of Chinese Medicine, Xiangya Hospital of Central South University, and Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine.

When is the study starting and how long is it expected to run for?
December 2009 to April 2011

Who is funding the study?
The study was funded by Jiangxi Qingfeng Pharmaceutical Co., Ltd.

Who is the main contact?
Ms Xiaonan Yang, West China Hospital of Sichuan University, yangxxnan@163.com

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Study information

Scientific Title
A randomized, double-blind, placebo-controlled, multicenter clinical study on the safety and efficacy of Aurantii Fructus Immaturus flavonoid extract tablets (Aolanti) in the treatment of functional dyspepsia (liver-stomach disharmony, damp-heat in spleen and stomach, and food stagnation syndromes)

Study objectives
Study and evaluate the efficacy and safety of Aurantii Fructus Immaturus flavonoid extract tablets (Aolanti) in treating functional dyspepsia (liver-stomach disharmony, spleen-stomach damp-heat, and food retention syndromes), and explore applicable syndrome types for phase III clinical trials.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/12/2009, Drug Clinical Trial Ethics Committee of West China Hospital of Sichuan University (No. 37, Guoxue Alley, Wuhou District, Chengdu, Sichuan Province, 610041, China; +86-28-85422114; hxjj@cd120.com), ref: 2008L04094

Study design
Stratified block-randomized double-blind single-simulation placebo parallel-controlled, multicenter clinical study

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
The treatment of patients with functional dyspepsia

Interventions
The study adopted a multicenter, randomized, double-blind, placebo-parallel-controlled design, with stratification factors including study center and TCM syndrome type. The ratio of the treatment group to the placebo group was 2:1 within each syndrome subtype.
This study divided patients into an experimental group and a control group. The experimental group received Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) with specifications of 0.29g/tablet (Batch No.: 20090625, provided by Jiangxi Qingfeng Pharmaceutical Co., Ltd.). The dosage was 4 tablets per dose, administered with warm water 30 minutes before meals, three times daily. The control group received a placebo with identical specifications (0.29g/tablet, Batch No.: 20090625, provided by Jiangxi Qingfeng Pharmaceutical Co., Ltd.), following the same administration regimen. The treatment course lasted 28 days, with follow-up visits every 7 days. A post-treatment follow-up period of 28 days was conducted.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti)

Primary outcome(s)
Western Medicine Disease Efficacy: Using the Western medicine primary symptom grading and quantification standards, the four main symptoms are graded and scored, with each symptom corresponding to a score of 0-3. Assessments are conducted at the screening period, baseline, and on days 7, 14, 21, 28, and 56, with a focus on evaluating the efficacy based on the scores at day 28.

Key secondary outcome(s))
1. Traditional Chinese Medicine (TCM) Syndrome Efficacy: Using the TCM syndrome grading and quantification standards, patients with syndromes such as Liver-Stomach Disharmony, Spleen-Stomach Dampness-Heat, and Food Retention are scored based on their symptoms. Assessments are conducted at the screening period, baseline, and on days 7, 14, 21, 28, and 56, with a focus on evaluating the efficacy based on the scores at day 28.
2. Gastric Emptying Time: The barium strip method is used to measure the gastric emptying rate at 3.5 hours. Observations and recordings are conducted once before medication (baseline) and once after 28 days of medication.
3. Changes in Tongue and Pulse Manifestations: A comprehensive inquiry and physical examination are conducted to observe changes in tongue and pulse before, during, and after treatment. Tongue manifestations are primarily assessed through visual inspection, observing the color of the tongue body and the condition of the tongue coating. Pulse manifestations are primarily assessed through palpation, where the patient's pulse is evaluated to determine its characteristics.

Completion date
30/04/2011

Eligibility

Key inclusion criteria
1. Sign the informed consent form
2. Meet the Western medical diagnostic criteria for functional dyspepsia
3. Conform to the Traditional Chinese Medicine (TCM) syndrome diagnostic criteria for epigastric stuffiness (including liver-stomach disharmony, spleen-stomach damp-heat, and food stagnation syndromes)
4. Aged 18 to 65 years at the time of enrollment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
265

Key exclusion criteria
1. Individuals with organic diseases such as esophagitis, atrophic gastritis, gastric and duodenal ulcers, erosions, tumors, etc.
2. Individuals with organic diseases of the liver, gallbladder, or pancreas
3. Individuals with diabetes, kidney disease, connective tissue disease, or psychiatric disorders
4. Individuals with severe primary diseases of the heart, brain, lungs, kidneys, hematopoietic system, or endocrine system
5. Individuals with a history of abdominal surgery
6. Pregnant women, those with pregnancy intentions, or women who are breastfeeding
7. Individuals with mental or legal disabilities
8. Individuals who have participated in other drug clinical trials within the 3 months prior to this trial

Date of first enrolment
01/03/2010

Date of final enrolment
08/12/2010

Locations

Countries of recruitment
China

Study participating centre
West China Hospital of Sichuan University
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Sponsor information

Organisation
Jiangxi Qingfeng Pharmaceutical Co., Ltd.

Funder(s)

Funder type
Industry

Funder Name
Jiangxi Qingfeng Pharmaceutical Co., Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The aggregated research data will be stored by the sponsor as required. The original research data will be retained at each research center in accordance with regulations. Interested parties may submit a request to the sponsor as needed, and the sponsor will provide relevant content based on actual circumstances. (Contact: Ms Qi, qitiancheng@qfyy.com.cn)

IPD sharing plan summary
Available on request