ISRCTN10266781 https://doi.org/10.1186/ISRCTN10266781

An exploratory clinical 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
06/03/2025

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 aimed to evaluate the safety and effectiveness of Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) in treating functional dyspepsia (FD), a chronic digestive disorder that causes pain and discomfort in the upper abdomen. The goal was to determine the optimal dosage for Phase III clinical trials.

Who can participate?
Patients aged 18 to 65 years with functional dyspepsia

What does the study involve?
Participants were divided into four groups: high-dose, medium-dose, low-dose, and placebo groups. The treatment duration was 28 days, with a follow-up period of 28 days for participants whose symptoms resolved.

What are the possible benefits and risks of participating?
Potential benefits included the alleviation of FD symptoms. Potential risks involved possible adverse drug reactions, although the study results indicated that the drug was well-tolerated with a favorable safety profile.

Where is the study run from?
Jiangxi Qingfeng Pharmaceutical Co., Ltd (China)

When is the study starting and how long is it expected to run for?
June 2011 to December 2012

Who is funding the study?
Jiangxi Qingfeng Pharmaceutical Co., Ltd (China)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A multicenter, randomized, double-blind, placebo-controlled, dose-exploratory clinical study on the safety and efficacy of aurantii fructus immaturus flavonoid extract tablets (Aolanti) in the treatment of functional dyspepsia

Study objectives
A placebo-controlled study to evaluate the efficacy and safety of high, medium, and low doses of Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) in the treatment of functional dyspepsia, and to explore the optimal dosage for Phase III clinical trials.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/07/2011, Clinical Trial Ethics Committee of West China Hospital of Sichuan University (No. 37 Guoxue Alley, Wuhou District, Chengdu, 610041, China; +86 (0)28 85422114; hxjj@cd120.com), ref: 2008L04094

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

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Functional dyspepsia

Interventions
Patients were divided into one of the experimental groups (high-dose group, medium-dose group, low-dose group) or the control group. A central block randomization method was employed. Using the SAS statistical analysis system, a random arrangement of treatments (experimental drug and control drug) for 400 subjects was generated. Specifically, a sequence of serial numbers from 001 to 400 was created, with each number corresponding to a treatment

allocation. Each center was assigned a continuous block of drug codes (exceptions may occur due to case reallocation caused by progress-related reasons).

Experimental Drug:
Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti), specification: 0.29 g/tablet, provided by Jiangxi Qingfeng Pharmaceutical Co., Ltd., batch number: 20110605.

Control Drug:
Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) placebo, specification: 0.29 g /tablet, provided by Jiangxi Qingfeng Pharmaceutical Co., Ltd., batch number: 20110605.

Dosage and Administration:
High-dose group: four tablets of Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) per dose, taken with warm water half an hour before meals, three times a day.
Medium-dose group: three tablets of Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) + one placebo tablet per dose, taken with warm water half an hour before meals, three times a day.
Low-dose group: two tablets of Aurantii Fructus Immaturus Flavonoid Extract Tablets (Aolanti) + two placebo tablets per dose, taken with warm water half an hour before meals, three times a day.
Placebo group: four placebo tablets per dose, taken with warm water half an hour before meals, three times a day.

Observation Period:
Treatment Duration: 28 days.
Follow-up: 28 days (only patients with all four symptoms resolved will undergo follow-up after discontinuation of the medication).

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
The percentage of disappearance of the four Western medical symptoms of functional dyspepsia (postprandial fullness, early satiation, epigastric burning, and epigastric pain) after 4 weeks of medication.
1. Functional dyspepsia symptoms (postprandial fullness, early satiation, epigastric burning) are scored as follows:
0 points: No symptoms
1 point: Mild symptoms that do not affect daily life
2 points: Moderate symptoms that do not significantly affect daily life
3 points: Persistent symptoms that significantly affect daily life
2. For epigastric pain, the Visual Analog Scale (VAS) is used:
A 10-cm straight line is employed, where the 0 cm end represents "no pain" and the 10 cm end represents "the most severe pain." Patients mark the point on the line that corresponds to their level of pain.

Key secondary outcome(s))
Gastric emptying assessed using radionuclide imaging: for selected centers (West China Hospital of Sichuan University and Xiangya Hospital of Central South University), radionuclide imaging is used to assess gastric emptying function. The 2-hour gastric emptying rate and half-emptying time are observed. The test is conducted and recorded once before medication and once after 28 days of medication. The 2-hour gastric emptying rate and half-emptying time (radionuclide imaging) are compared between groups.

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Age ≥18 years and ≤65 years, regardless of gender
2. Voluntarily participate and sign the written informed consent form
3. Meet the diagnostic criteria for functional dyspepsia
4. Discontinuation of other prokinetic agents, gastroprotective agents, or acid-suppressing drugs for at least 4 weeks prior to 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
399

Key exclusion criteria
1. Individuals with organic diseases such as esophagitis, atrophic gastritis, gastric and duodenal ulcers, erosions, bleeding, 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. Individuals with renal insufficiency, with creatinine (Cr) levels above the upper limit of normal

7. Individuals with hepatic insufficiency, with AST and/or ALT levels 1.5 times the upper limit of normal
8. Pregnant women, those with pregnancy intentions, or women who are breastfeeding
9. Individuals with mental or legal disabilities
10. Individuals who have participated in other drug clinical trials within the 3 months prior to this trial

Date of first enrolment
19/10/2011

Date of final enrolment
25/09/2012

Locations

Countries of recruitment
China

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Study participating centre
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The First Affiliated Hospital of Hunan University of Chinese Medicine
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Study participating centre

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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: Qi,qitiancheng@qfyy.com.cn)

IPD sharing plan summary
Available on request