

Efficacy and Safety of Prunella Oral Liquid in the Treatment of Thyroid Nodules

NCT06423235

Status	RECRUITING
Phase	Phase 4
Sponsor	Xintian Pharmaceutical
Enrollment	234 participants

Key Eligibility Criteria

Inclusion (6)

- years old ≥65 years old;
- Thyroid ultrasonography found thyroid nodules, may be accompanied by goiter, and the nodules meet the following conditions: 1) single nodules, or dominant nodules in multiple nodules (the largest diameter of the second largest nodules does not exceed 50% of the largest nodules), 2) solid nodules, 3) the longest diameter of nodules ≤1cm and < 3cm, 4) C-TIRADS 3~4A nodules;
- Patients who met the puncture indications were confirmed by fine needle aspiration biopsy (FNAB) as benign nodules (Bethesda Class II);
- Serum TSH, free thyroid hormone (FT3, FT4) levels were normal, anti-thyroglobulin (TgAb) and anti-thyroid peroxidase (TPOAb) antibody titers were normal;
- Meet the diagnostic criteria of thyroid nodules in TCM;
- ... and 1 more (see full listing online)

Exclusion (12)

- Exclude the patients with Deficiency of Yang syndrome, and the following two conditions can be diagnosed: Shortness of breath, abdominal pain and diarrhea, diarrhea with undigested food, Insufficiency with chills, exhaustion and lethargy, pale tongue and white fur, deep and weak pulse
- Those who have reproductive needs during pregnancy, lactation and within the last 12 months;
- Patients with high possibility of thyroid cancer indicated by ultrasonic signs and malignant confirmed by fine needle biopsy;
- Patients who meet the indications for thyroid nodule surgery, such as local compression symptoms obviously related to the nodule, the tumor is located behind the sternum or in the mediastinum, or strongly require surgery due to appearance or ideological concerns affecting normal life;
- Patients who have taken prunella preparations or other similar Chinese medicines to treat the disease within the past 1 month; Patients using glucocorticoids in the last 3 months;
- ... and 7 more (see full listing online)

Locations (22 total)

Second Hospital of Army Military Medical University, Chongqing, Chongqing Municipality, China
Xiamen Hospital of Traditional Chinese Medicine, Xiamen, Fujian, China
People's Hospital of Guangdong Province, Guangzhou, Guangdong, China
... and 19 more locations

<https://clinicaltrials.gov/study/NCT06423235>

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