

**Clinical Observation Of The Gynecological
Iron-Deficiency Anemia Treated With
Buxue Yimu Pills**

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A. OBJECT

Buxue Yimu Pills, Ferrous Sulfate each improve anemia, but they do so by different mechanisms. We generally treat patients with uncomplicated Iron Deficiency Anemia with oral iron due to the ease of administration, and Ferrous Sulfate is one of the most commonly used drugs.

Buxue Yimu Pills consists of multiple Chinese herbs including Angelica Sinensis, Astragalus, Donkey-Hide Gelatin, Herba Leonuri, Citrus etc., which gains widespread application in the treatment after women's abortion or operations of uterine cavity.

This study evaluates Buxue Yimu Pills, Ferrous Sulfate and the addition of Buxue Yimu Pills to Ferrous Sulfate in the treatment of Iron-Deficiency Anemia in adult women, with the object to perform clinical efficacy and safety assessment. In addition, we expect to conduct research on its pharmacodynamics, trying to probe into the mechanism and pharmacodynamic material basis of this mysterious traditional Chinese medicine.

B. STUDY DESIGN AND METHOD

— **STUDY DESIGN:** 180 women with mild to moderate Iron Deficiency Anemia were observed in a prospective multi-center randomized controlled clinical trial.

Inclusion Criteria:

1. Subject is a female between the age of 18 and 50.
2. Subject suffers from mild to moderate anemia with a hemoglobin between 80g/L and 110 g/L.
3. Subject has definite gynecological etiological factors of iron deficiency
4. Subject provides written informed consent.

Exclusion Criteria:

1. Subject underwent chronic digestive tract inflammation, uncontrolled digestive or urinary system bleeding.
2. Subject has other complications in addition to gynecological diseases leading to iron deficiency, such as hemorrhagic diseases of hematologic system, parasitic diseases like ancylostomiasis, chronic intravascular hemolysis, mechanical hemolysis like prosthetic valve, renal dysfunction and hemodialysis.
3. Subject is pregnant or lactating.
4. Subject has a severe systemic disease, such as cardiovascular system
5. Subject has a history of malignancy or radiotherapy.
6. Subject has undergone any Iron deficiency anemia treatment including Iron supplements or blood transfusion within 1 month prior to randomization.
7. Subject has mental disorder incapable of elementary cooperations.
8. Subject has participated in other clinical researches of medicine within 1 month prior to randomization.

—**METHODS:** The participants were divided randomly into 3 groups:

- a. Experimental group1(60 patients): Buxue Yimu Pills 12g pill by mouth, twice daily.
- b. Experimental group2(60 patients): Buxue Yimu Pills 12g pill by mouth, twice daily and Ferrous Sulfate 0.3g tablet by mouth, three times daily.
- c. Active Comparator group (60 patients): Ferrous Sulfate 0.3g tablet by mouth, three times daily.

—**TREATMENT PERIOD:** 1month.

—**OUTCOMES MEASUREMENT :**

Primary Outcome (Anemia Related Assessment, Clinical Efficacy Assessment): Complete Blood Count, Urine Routine, Reticulocyte Count, Iron Metabolism index (Serum Iron, Total Iron Binding Capacity, Serum Ferritin), Coagulation Indexes (Activated Partial Thromboplastin Time, APTT), Prothrombin Time (PT), Fibrinogen (FIB), Thrombin Time(TT), The Short Form-36 Health Survey (Sf-36).

Secondary Outcome (Safety Assessment): Hepatic Function, Renal Function, Blood Glucose, Electrolyte Semiconductor Junction, Electrocardiogram(ECG)

Other Pre-Specified Outcome (Metabonomics Assessment): Build up a new therapeutic evaluation system about Buxue Yimu Pills in the treatment of Gynecological Iron-Deficiency Anemia, which integrating clinical information with metabonomics, to probe into the mechanism and pharmacodynamic material basis of this mysterious traditional Chinese medicine.

C. TECHNICAL ROUTE

Screening Period (Day -30~0)

1. We enrolled in-patients according to the uniform inclusion/ exclusion criteria above, and informed consent will be signed by all study participants before joining in the study.
2. Collect medical history and certain demographic features of every participant, and perform general physical examination as well as gynecologic physical examination.
3. Complete outcomes measurement above.
4. Make the appointment for the follow-up.

The First Follow-Up Period (Day -30~0)

1. Group randomly and distribute medicine and patient diary pamphlet.
2. Inform application notice.
3. Make the appointment for the next follow-up.

The Second Follow-Up Period(Day0~30)

1. Collect medical history and certain demographic features of every participant, and perform general physical examination as well as gynecologic physical examination, again.
2. Complete outcomes re-measurement above.
3. Take back the medicine and patient diary pamphlet.

D. STATISTICS ANALYSIS

Data was analyzed using SPSS Version 18. All quantitative informations are expressed as mean values \pm standard deviation (SD). Statistical significance was assessed using unpaired Student's t-test or chi-square test. Probability values of less than 0.05 were considered significant and an asterisk identifies such significance in the figures. We will also compare the adverse effect of each group using descriptive statistics.

E. QUALITY CONTROL MEASUREMENT AND RESULT PUBLICATION

1. Every center of the research possesses the competence of scientific research to conduct clinical studies. Special people from each center will be put in charge of the research and monitoring the whole procedure. The rights and interests, responsibility and obligation of all centers will be standardized with the research agreement.
2. The maintenance, secrecy and safety of data and informations will be guaranteed by Department of Obstetrics and Gynecology, Peking Union Medical College Hospital.
3. Every center is responsible to subject enrollment and finish the prospective follow up.
4. The researchers' findings will be released in a paper published online.

F. SOURCE(S) OF FUNDING

1. This study does not charge any fee to any patients.
2. All the investigational drugs and cost of the study are provided by Qian Jin Pharmaceutical CO., LTD.