INPLASY PROTOCOL

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Corresponding author:
Wei Liu

weiweiwei666888@gmail.com

Author Affiliation:
Integrative medicine.

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None declared.

The efficacy of Xuefu Zhuyu decoction combined with trimetazidine on unstable angina pectoris: A meta-analysis of randomized clinical trials

Liu, W[1]; Li, X[2]; Fan, Z[3]; Cui, J[4]; Wu, Y[5].

Review question / Objective: **1. Types of studies - We will collect all available randomized controlled trials (RCTS) on Xuefu Zhuyu decoction combined with trimetazidine for the treatment of unstable angina pectoris, regardless of blinding, publication status, or region, but the language is limited to Chinese and English. 2. Research subjects - Patients diagnosed as unstable angina pectoris according to the diagnostic criteria of CHD, excluding patients with other severe heart, liver and kidney dysfunction, and drug allergy. However, the patient's nationality, race, age, sex, course of disease are unlimited. 3. Interventions - The control group: use trimetazidine treatment alone, the type, dosage, course of treatment is not limited. The treatment group: use Xuefu Zhuyu decoction on the basis of which in the control group, the dosage form, dosage, addition and subtraction of Xuefu Zhuyu decoction is not limited. 4. Outcome indicators - Total efficiency, frequency of angina pectoris and duration of angina pectoris.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 March 2021 and was last updated on 21 March 2021 (registration number INPLASY202130073).

INTRODUCTION

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the diagnostic criteria of CHD, excluding patients with other severe heart, liver and kidney dysfunction, and drug allergy. However, the patient's nationality, race, age, sex, course of disease are unlimited. 3. Interventions - The control group: use trimetazidine treatment alone, the type, dosage, course of treatment is not limited. The treatment group: use Xuefu Zhuyu decoction on the basis of which in the control group, the dosage form, dosage, addition and subtraction of Xuefu Zhuyu decoction is not limited. 4. Outcome indicators - Total efficiency, frequency of angina pectoris and duration of angina pectoris.

Condition being studied: Unstable angina pectoris. 1. All the conditions required for this study have been met. 2. This stydy is feasible and Researchable. 3. This study has a scientific research plan. 4. This study has professional personnel, equipment and venues.

METHODS

Participant or population: Patients diagnosed as unstable angina pectoris.

Intervention: The control group: use trimetazidine treatment alone, the type, dosage, course of treatment is not limited. The treatment group: use Xuefu Zhuyu decoction on the basis of which in the control group, the dosage form, dosage, addition and subtraction of Xuefu Zhuyu decoction is not limited.

Comparator: Total efficiency, frequency of angina pectoris and duration of angina pectoris.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Patients diagnosed as unstable angina pectoris according to the diagnostic criteria of CHD, excluding patients with other severe heart, liver and kidney dysfunction, and drug allergy. However, the patient's nationality, race, age, sex, course of disease are unlimited.

Information sources: Search PubMed, EMbase, The Cochrane Library, CNKI, VIP, WANFANG DATA for information about clinical randomized controlled trials (RCTs) of Xuefu Zhuyu decoction combined with trimetazidine for the treatment of unstable angina pectoris through computer.

Main outcome(s): Effective: After treatment, the frequency of angina attack was significantly reduced, other symptoms were significantly improved, and laboratory indicators showed significant improvement; Invalid: not up to the above standard. Total effective rate = (number of significant cases + number of effective cases)/total number of cases 100%.

Quality assessment / Risk of bias analysis: Risk Bias assessment was carried out for the included studies using the Risk of Bias assessment tool recommended by the Cochrane Reviewers Handbook 5.1.0. According to the performance of Random sequence generation, Aliocation concealment, Blinding of participants and personal, Blinding of outcome assessment, Incomplete outcome data, Selective reporting, Other bias and other aspects, the two researchers independently gave low risk, unclear and high risk judgment item by item, and carried out cross-checking after completion respectively. If there was any difference, they agreed with the third researcher.

Strategy of data synthesis: The RevMan5.3 software provided by Cochrane collaboration network will be used to meta-analyze the extracted data. For continuous variables, if the unit or measuring tool of the measurement index is consistent, the mean difference (MD) is used as the statistic, and if not, the standard mean difference (SMD) is used as the statistic. The relative risk degree (RR) is used as the effect analysis statistic, the $\chi 2$ test is used for the heterogeneity among the included studies, and I2 is used to quantitatively judge the heterogeneity between studies. If ($P \geq .1$, $I2 \leq 50\%$), the heterogeneity among studies is low, and the fixed-effect model is used for Meta analysis; if ($P < .1$, $I2 > 50\%$), it is indicated that there is significant

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heterogeneity the studies, and the source of heterogeneity should be further analyzed.

Subgroup analysis: If there is obvious clinical heterogeneity, subgroup analysis is carried out; if clinical heterogeneity is obvious and subgroup analysis cannot be carried out, meta-analysis is not carried out, only descriptive analysis is used; if there is no obvious clinical and methodological heterogeneity, statistical heterogeneity should be considered and random effect model is used for meta-analysis.

Sensitivity analysis: Sensitivity analysis was used to observe the effect of single outcome index on the amount of combined effect to judge the stability of meta-analysis results.

Country(ies) involved: China.

Keywords: Xuefu Zhuyu decoction; trimetazidine; unstable angina pectoris; Meta-analysis.

Contributions of each author:
Author 1 - Wei Liu.
Author 2 - Xingxing Li.
Author 3 - Zongjing Fan.
Author 4 - Jie Cui.
Author 5 - Yang Wu.

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