

INPLASY PROTOCOL

To cite: Yang et al. Comparison of efficacy and safety of Traditional Chinese patent medicine in the treatment of vitiligo in children or adults A protocol for systematic review and network meta-analysis. Inplasy protocol 2020120050. doi: 10.37766/inplasy2020.12.0050

Received: 08 December 2020

Published: 09 December 2020

Corresponding author:
Meng Yang

syqiangs@163.com

Author Affiliation:
Affiliated Hospital of
Shandong University of
Traditional Chinese Medicine,
No. 16369, Jingshi Road, Jinan
City, Shandong Provinc

Support: 2011-056.

Review Stage at time of this submission: The review has not yet started.

Conflicts of interest:
We declare no conflicts of interest.

INTRODUCTION

Review question / Objective: Vitiligo is a common depigmented skin disease in children or adults, which usually causes

Comparison of efficacy and safety of Traditional Chinese patent medicine in the treatment of vitiligo in children or adults A protocol for systematic review and network meta-analysis

Yang, M¹; Du, MM²; Tang, ZK³; Han, GQ⁴; Dong, WY⁵; Chen, ZY⁶; Song, YQ⁷.

Review question / Objective: Vitiligo is a common depigmented skin disease in children or adults, which usually causes considerable psychological burden to life and work for the reason that it affects appearance. The conventional therapies, including external 308nm excimer laser therapy along with oral administration of western medicine, are associated with distinct disadvantages. Notably, traditional Chinese patent medicine (TCPM) exerts a vital part in treating vitiligo. Currently, no existing research has examined the effectiveness and safety of different TCPMs in treating vitiligo among either child or adult patients. As a result, the present network meta-analysis was carried out for the systematic comparison of the effectiveness of different TCPMs in treating vitiligo.

Condition being studied: Vitiligo refers to the frequently seen depigmentation disorder of skin resulting from the declined or lost functional melanocytes in the skin and / or hair follicles. The typical manifestation of skin lesions is depigmentation spots of varying size and number, and the prevalence rate is approximately 1%.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 December 2020 and was last updated on 09 December 2020 (registration number INPLASY2020120050).

considerable psychological burden to life and work for the reason that it affects appearance. The conventional therapies, including external 308nm excimer laser therapy along with oral administration of

western medicine, are associated with distinct disadvantages. Notably, traditional Chinese patent medicine (TCPM) exerts a vital part in treating vitiligo. Currently, no existing research has examined the effectiveness and safety of different TCPMs in treating vitiligo among either child or adult patients. As a result, the present network meta-analysis was carried out for the systematic comparison of the effectiveness of different TCPMs in treating vitiligo.

Condition being studied: Vitiligo refers to the frequently seen depigmentation disorder of skin resulting from the declined or lost functional melanocytes in the skin and / or hair follicles. The typical manifestation of skin lesions is depigmentation spots of varying size and number, and the prevalence rate is approximately 1%.

METHODS

Participant or population: Child or adult patients with vitiligo were enrolled. Anxiety was diagnosed following Vitiligo disease activity score (VIDA), clinical features, homomorphic reaction, Wood lamp examination results, laser confocal scanning microscope (CT) and dermatoscope image changes.

Intervention: Patients in experimental group were given TCPMs in combination with traditional western medicine (WM). In the present study, the TCPMs adopted were Bailing pill, qubaibabusi pill, baishi capsule and fufangquchongbanjiuju capsule.

Comparator: WM treatment alone was applied for control group, including oral western medicine and external 308nm excimer laser therapy.

Study designs to be included: Child or adult patients with vitiligo were enrolled. Anxiety was diagnosed following Vitiligo disease activity score (VIDA), clinical features, homomorphic reaction, Wood lamp examination results, laser confocal

scanning microscope (CT) and dermatoscope image changes.

Eligibility criteria: We will include the criteria: 1) patients diagnosed with vitiligo; 2) patients in the experimental group were treated with traditional chinese patent medicine on the basis of traditional western medicine. 3) The control group was treated with traditional western medicine. 4) The type of study was randomized controlled trial.

Information sources: The electronic databases, like PubMed, Web of Science, EMBASE, The Cochrane Library, Chinese Scientific Journals Database (VIP), China National Knowledge Infrastructure (CNKI), Wanfang database and China BioMedical Literature (CBM), were searched systemically by two reviewers independently from inception to August 2020 to identify relevant RCTs according to our study inclusion criteria. In data extraction, risk of bias among those enrolled articles was also detected. Besides, the Bayesian network meta-analysis method was utilized to evaluate the evidence and data collected. This adopted the STATA and WinBUGS software for analysis. Results: The present work assessed the safety and efficacy of different TCPMs in treating vitiligo among child or adult patients. Conclusion: Our findings can shed precious lights on applying TCPMs in clinic and help the clinicians to formulate the efficient diagnostic and therapeutic strategies. Ethics and dissemination: No ethical approval was needed in this study. INPLASY registration number: -----
Abbreviations: CI=confidence interval, CNKI=Chinese national knowledge infrastructure, CBM=Chinese biomedical literature database, NMA=network meta-analysis, MD=mean difference, OR=odds ratio, RCT= randomized controlled trial, SMD=standardized mean difference, SE=standard error, TCPM=traditional Chinese patent medicine. Keywords: Vitiligo in children or adults, network meta-analysis, protocol, Traditional Chinese patent medicine(TCPM) 1. Introduction

Vitiligo refers to the frequently seen depigmentation disorder of skin resulting from the declined or lost functional melanocytes in the skin and / or hair follicles. The typical manifestation of skin lesions is depigmentation spots of varying size and number, and the prevalence rate is approximately 1%[1]. In particular, the skin lesions of exposed areas such as face and neck seriously damage the appearance of patients. Patients with vitiligo usually have depression and anxiety, and this may result in social isolation or the sense of inferiority[2]. According to a survey of its members conducted by the British Vitiligo Association, 57% of respondents said vitiligo exerted a moderate or severe

Main outcome(s): According to the Vitiligo disease activity score (VIDA), clinical features, homomorphic reaction, Wood lamp examination results, laser confocal scanning microscope (CT) and dermatoscope image changes, all the enrolled articles should mention at least one main indicators.

Quality assessment / Risk of bias analysis: Two reviewers evaluated the trial quality independently in line with the Cochrane Risk of Bias Risk Assessment Tool mentioned in the Cochrane Handbook version 5.1.0. In addition, the trial quality was assessed using the decision words such as “low risk”, “high risk” or “unclear risk” from 7 perspectives, namely, blinding; sufficiency of random sequence; allocation concealment; selective reporting; complete result information; bias of publication; and others.

Strategy of data synthesis: The Markov chain-Monte Carlo (MCMC) approach was adopted in this study for Bayesian meta-analysis using the Stata 14.0 software. Altogether 3 Markov chains were utilized in simulation for 50,000 iterations (the initial 20,000 were carried out for annealing and eliminating the original value impact, whereas the final 30,000 were adopted in sampling). We employed Stata 15.0 to draw the reticular diagram for directly and indirectly comparing diverse interventional measures. Relative odds ratio (RoR),

together with the corresponding 95% confidence intervals (CIs), was determined for evaluating the closed loop consistency. As for 95% CI, its lower limit was 1, which indicated high consistency. Besides, a RoR value approximating 1 suggested the consistency between indirect and direct evidence; in this case, a fixed effect model was used. On the contrary, a random effect model was adopted due to the distinct inconsistency. Dichotomous data were presented as odds ratio (OR) together with the corresponding 95% CI. A difference of $P < 0.05$ indicated statistical significance. The effectiveness of diverse interventional measures was ranked using WinBUGS 1.4.3. The area under the curve (AUC), which was presented in the manner of percentage, was determined, with a higher value indicating a superior effect.

Subgroup analysis: In the presence of enough data, subgroup analysis was conducted.

Sensibility analysis: In addition, we also performed sensitivity analysis based on the symptom improvement rate for evaluating the methodology and clinical similarity among the enrolled articles, thus determining whether our results were creditable.

Country(ies) involved: China.

Keywords: Vitiligo in children or adults, network meta-analysis, protocol, Traditional Chinese patent medicine (TCPM).

Contributions of each author:

Author 1 - Meng Yang - The author is responsible for data collection, statistical analysis and drafting.

Email: ymhappyday@163.com

Author 2 - Mengmeng Du - The author is responsible for data collection, statistical analysis and drafting.

Email: 1634973843@qq.com

Author 3 - Zhikun Tang - The author is responsible for data collection.

Email: szytzk@163.com

Author 4 - Guanqing Han - The author is responsible for the information feedback and the final manuscript.

Email: 1119145454@qq.com

Author 5 - Wenyao Dong - The author is responsible for data collection.

Email: dongwenyao@163.com

Author 6 - Zhaoyu Chen - The author is responsible for the information feedback and the final manuscript.

Email: 1355120514@qq.com

Author 7 - Yeqiang Song - The author is responsible for fund support.

Email: syqiangs@163.com