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Evaluation of Chinese medicine prescriptions for intervention in precocious puberty based on clinical cases and network meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Jiangxi University of Traditional Chinese Medicine.

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202450032

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 May 2024 and was last updated on 09 May 2024.

INTRODUCTION

Review question / Objective we aimed to summarize the current clinical drug regimens for the treatment of precocious puberty in children, systematically evaluate the clinical efficacy of a variety of Chinese herbal compounds combined with gonadotropin-releasing hormone analog (GnRHa)-based Western medicines, and compare the characteristics and target indicators of different Chinese herbal compounds to provide recommendations for the use of Chinese herbal compounds in clinical drug therapy.

P-precocious puberty in children

I-Chinese medicine prescriptions with GnRHa

C-use GnRHa only

S-randomized controlled trial.

Rationale Based on clinical electronic medical records and the literature, we aimed to summarize the current clinical drug regimens for the treatment of precocious puberty in children, systematically evaluate the clinical efficacy of a variety of Chinese herbal compounds combined with gonadotropin-releasing hormone analog (GnRHa)-based Western medicines, and compare the characteristics and target indicators of different Chinese herbal compounds to provide recommendations for the use of Chinese herbal compounds in clinical drug therapy.

Condition being studied The incidence of precocious puberty is increasing year by year, however, conventional drug treatment has certain risks and high treatment cost. Traditional Chinese medicine (TCM) is effective and safe in treating precocious puberty.

METHODS

Search strategy SU=(("性早熟"+"早发育"+"青春期早发育"+"第二性征提前"+"CPP"+"ICPP"+"中枢性性早熟"+"外周性性早熟")*(("中医药"+"中成药"+"中草药"+"中药"+"草药"+"方剂"+"汤"+"颗粒剂"+"散"+"丸"+"膏"+"酒"+"饮片"+"饮"+"丹"+"茶"+"药露"+"锭"+"饼"+"糖浆"+"片"+"冲剂"+"胶囊"+"贴剂"+"中药漏渍"+"熏洗"+"涂敷"+"毫包"+"热熨"+"擦拭"+"药袋疗法").

Participant or population Children with precocious puberty.

Intervention Chinese medicine prescriptions with GnRHa.

Comparator Use GnRHa only.

Study designs to be included Cross-sectional studies.

Eligibility criteria The inclusion criteria: ① studies that met the diagnostic criteria of the National Clinical Treatment Guidelines for Precocious Puberty; ② studies in which the intervention group received a combination of TCM compounds combined with GnRHa-based Western medicines, and the the control group received GnRHa-based Western medicines alone; ③ studies in which the outcome indicators included the therapeutic efficacy indicators included in the guidelines for the treatment of precocious puberty; and ④ randomized controlled trials (RCTs).

The exclusion criteria: ① non-RCT studies, conferences, scientific and technological achievements, reviews, etc.; ② studies in which the intervention in the treatment group involved the use of herbal compounds alone; and ③ studies with inaccurately described results or outcome indicators that did not meet the efficacy criteria contained in the clinical guidelines.

Information sources Hospital electronic medical cases database, China National Knowledge Infrastructure (CNKI), Beijing Wanfang, Chongqing VIP, CBM, PubMed, Web of Science, and Cochrane Library databases.

Main outcome(s) The efficacy of traditional Chinese medicine compound formulas combined with GnRHa-based Western medicines for the treatment of precocious puberty is greater than that of Western medicines alone. The most

effective auxiliary compound formula commonly used in the clinic is Zhi Bai Di Huang pills plus and minus the formula, whereas Dan Zhi Xiao Yao capsules help to lower the levels of sex hormones, and Da Bu Yin pills help to improve bone development in children experiencing precocious puberty, with better effects.

Quality assessment / Risk of bias analysis Cochrane collaboration s tool for assessing risk of bias.

Two researchers independently evaluated the risk of bias included in the study and cross-checked the results. If there are differences, a third party shall negotiate and resolve them. The bias risk assessment was conducted using the RCT bias risk assessment tool and JBI bias risk assessment tool recommended in Cochrane Handbook 5.10. The evaluation tool includes 7 items: 1) Whether the random sequence generation method is appropriate, 2) Whether allocation concealment is correctly implemented, 3) Whether blinding is correctly applied to patients and doctors, 4) Whether blinding is correctly applied to result evaluators and analysts, 5) Whether results are reported without selectivity, 6) Whether the result data is complete, and 7) Whether there is any other risk of bias. If the result is determined to be definitive yes indicating low bias risk and definitively no indicating high bias risk, for items that cannot be determined for bias risk due to lack of direct information, we will infer from other information in the literature that the item is at risk of bias for both probability “yes” and probability “no”.

Strategy of data synthesis Stata15.1.

Subgroup analysis None.

Sensitivity analysis First High-risk articles were excluded before analysis, Second the fixed effect model was replaced by the effect model.

Language restriction There are no restrictions on languages.

Country(ies) involved China.

Keywords children; precocious puberty; cross-sectional study; literature study; network meta-analysis; herbal compounds.

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