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The efficacy of placebo in clinical trials of topical minoxidil for androgenetic alopecia: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - National Natural Science Foundation of China.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202420015

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 February 2024 and was last updated on 04 February 2024.

INTRODUCTION

Review question / Objective P: androgenetic alopecia; I: placebo; C: / ; O: target area non-vellus hair count; S: randomized controlled trial.

Condition being studied Androgenetic alopecia, characterized by progressive hair loss, is the most common form of alopecia that affects both men and women, associated with significant impairment in quality of life.

METHODS

Search strategy ("Alopecia"[Mesh] OR androgenetic alopecia[Title/Abstract] OR pattern alopecia[Title/Abstract] OR pattern baldness[Title/Abstract] OR (androgenic alopecia[Title/Abstract]) AND ("Minoxidil"[Mesh] OR minoxidil[Title/Abstract]) AND (randomized controlled trial[Publication Type] OR randomized[Title/Abstract] OR placebo[Title/Abstract]).

Participant or population Inclusion criteria were as follows: (a) humans of any gender and a confirmed physician's diagnosis of AGA; (b) randomized controlled trials; (c) the study on clinical efficacy of placebo groups of topical minoxidil in AGA clinical trials; and (d) assess efficacy with change of TAHC from baseline. Subjects were excluded if they had alopecia from other causes, history of surgery or other drugs for alopecia.

Intervention Record the type of placebo treatment, how frequently it was administered, and route of administration.

Comparator None.

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Study designs to be included Randomized controlled trial.

Eligibility criteria Inclusion criteria were as follows: (a) humans of the confirmed physician's diagnosis of AGA; (b) randomized controlled trials; (c) the study on clinical efficacy of placebo groups of topical minoxidil in AGA clinical trials; and (d) assess efficacy with the change of TAHC from baseline. Subjects were excluded if they had alopecia from other causes, history of surgery or other drugs for alopecia.

Information sources PubMed, EMBASE, Cochrane Central Register of Controlled Trials and Web of Science.

Main outcome(s) The change of target area non-vellus hair count (TAHC), defined as non-vellus target area hair count from baseline, among patients not receiving active treatment, by visual inspection, digital phototrichogram, etc.

Quality assessment / Risk of bias analysis Risk of bias was systematically assessed for each study using Cochrane guidelines. Each study was assessed independently by 2 investigators for 7 domains of bias (random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias) and designated as low risk, unclear risk, or high risk. Any discrepancies were discussed till consensus.

Strategy of data synthesis All extracted data will be independently entered by two investigators and conducted using the Review Manager 5.4.. Continuous outcomes will be expressed in terms of the standard mean difference with 95% confidence intervals (CIs). Statistical Heterogeneity among the summary data will be tested using the χ^2 and I2 statistics, and we will conduct sensitivity analyses to assess the robustness of results. Outcomes will be pooled using random effects model or fixed effects model. We will check all the data and methodology of the study to judge the source of heterogeneity when significant heterogeneity will be detected. $P < .05$ is considered statistically significant. Adhering to the Preferred Reporting Items for Systematic reviews and Meta-analysis diagram.

Subgroup analysis Subgroups may be divided by sex, follow-up time or hair counting measures.

Sensitivity analysis We will perform influence analysis by omitting one study in each analysis to determine the individual impact on the overall pooled result. Publication bias will be evaluated using the Egger linear regression approach and funnel plots.

Language restriction English.

Country(ies) involved China.

Keywords Placebo, androgenetic alopecia, meta-analysis.

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