INPLASY PROTOCOL

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Support: At our own expense.

Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

Conflicts of interest: None declared.

Relative efficacy of minoxidil and 5-alpha-reductase inhibitors in the treatment of male androgenetic alopecia: protocol for a network meta-analysis study

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Review question / Objective: There are numerous treatments for androgenetic alopecia (AGA), a form of hair loss many men are diagnosed with; among the repertoire of therapies are minoxidil, dutasteride and finasteride—the latter two of which are 5-alpha-reductase inhibitors (5ARIs). In a network meta-analysis (NMA), the efficacy of three or more treatments can be simultaneously compared to determine the relative efficacy thereof. The objective of the proposed NMA study is to determine the relative efficacy of minoxidil, dutasteride and finasteride in the treatment of male AGA.

Condition being studied: Androgenetic alopecia in men—which can also be referred to as male AGA.

INTRODUCTION

Review question / Objective: There are numerous treatments for androgenetic alopecia (AGA), a form of hair loss many men are diagnosed with; among the repertoire of therapies are minoxidil, dutasteride and finasteride—the latter two of which are 5-alpha-reductase inhibitors (5ARIs). In a network meta-analysis (NMA), the efficacy of three or more treatments can be simultaneously compared to determine the relative efficacy thereof. The objective of the proposed NMA study is to

determine the relative efficacy of minoxidil, dutasteride and finasteride in the treatment of male AGA.

Rationale: The objective of the proposed work focuses on minoxidil and the 5ARIs because there is paucity of evidence regarding their relative efficacy; for example, controlled trials on oral minoxidil for male AGA are non-existent; there are no head-to-head studies that compare the therapeutic impact of the oral and topical forms of minoxidil in men with AGA. Hence, a NMA is valuable because this statistical tool is a time-efficient approach to producing evidence on relative efficacy without financial and/or ethical constraints.

Condition being studied: Androgenetic alopecia in men—which can also be referred to as male AGA.

METHODS

Participant or population: Our population of interest is males—of any age and ethnicity—who are diagnosed with AGA.

Intervention: Our interventions of interest are minoxidil, dutasteride and finasteride; these can be of any concentration (i.e., dose) and route of administration (e.g., topical or oral).

Comparator: Minoxidil and the 5ARIs can be compared with vehicle (or placebo) (e.g., minoxidil 2% vs. vehicle) or with themselves (e.g., minoxidil 0.25mg vs. dutasteride 0.5mg); vehicle and placebo will be amalgamated into one group.

Study designs to be included: Data for the proposed study will be obtained from randomized studies (multi-arm and head-to-head) and single-arm trials.

Eligibility criteria: Studies that will be eligible for our NMAs will be ones that investigate minoxidil, dutasteride or finasteride in men with AGA.

Information sources: The literature will be systematically searched in PubMed and Google Scholar.

Main outcome(s): The proposed study will have 4 endpoints and they are: the change in hair count (total and terminal) after 24 and 48 weeks of therapy.

Additional outcome(s): None.

Quality assessment / Risk of bias analysis: Studies that are eligible for quantitative analyses will be assessed for quality of evidence individually and collectively. Within-study risk of bias (RoB) will be assessed using Cochrane's RoB table in the Review Manager software (version 5.4). Quality of evidence across each network will be evaluated using the recently developed Confidence in Network Meta-Analysis (CINeMA) approach, a tool which uses the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework.

Strategy of data synthesis: A NMA will be conducted for each outcome under a Bayesian random-effects model. The four NMAs will be conducted with the gemtc package for the RStudio software (version 1.3.959); arm-level data will be inputted, where each row would have information on the study, intervention, sample size, mean difference (i.e., change in hair count from baseline) and standard deviation. Results from our quantitative analyses will be presented in league tables and Kilim plots. For each of the four outcomes, relative efficacy will be ranked using each treatment's surface under the cumulative ranking curve (SUCRA) value. For all analyses, alpha will be set to 5%. Observational studies will be connected to our network of randomized evidence by matching on relevant baseline characteristic(s)—and data will be combined through naïve pooling.

Subgroup analysis: None.

Sensitivity analysis: None.

Language: Works from the non-English language literature will be excluded.

Country(ies) involved: Canada.

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Conflicts of interest: Mediprobe Research Inc. is a not-for-profit, non-commercial research group. Dr. Aditya Gupta, Ms. Maanasa Venkataraman, Dr. Mesbah Talukder, and Dr. Mary Bamimore have no conflict of interests to declare.