INPLASY PROTOCOL

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

Conflicts of interest: None declared. Effectiveness of Multimodality Therapy using Minoxidil and Microneedling for the Treatment of Alopecia: A Systematic Review and Meta-analysis

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Review question / Objective: To test the effectiveness of multimodality therapy using minoxidil and micmroneedling, in comparison to minoxodil alone for the treatment of alopecia. In terms of the PICO framework: Population: Includes patients with any form of clinically diagnosed alopecia. Intervention: Includes using combination therapy with microneedling and minoxidil in the treatment of alopecia. Comparison: Includes comparison to minoxidil alone as control group. Outcome: Primary outcome: Increased hair density. Secondary outcome: Increased hair diameter.

Condition being studied: Alopecia (hair loss) is a condition that is frequently seen in dermatology. When a thorough examination is made, the root of the issue is frequently revealed, allowing for an explanation and the most suitable treatments. Nevertheless, hair loss can occasionally be the first indicator of a serious underlying medical problem, be observed in conjunction with other conditions, or be a side effect of treatment. Furthermore, alopecia may result in distressingly noticeable symptoms, cause significant patient distress, and cause alopecia with lifelong scars and irreversible hair loss. Therefore, with these illnesses, a precise diagnosis and quick therapy are essential for the most beneficial outcomes.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 January 2023 and was last updated on 11 January 2023 (registration number INPLASY202310031).

INTRODUCTION

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comparison to minoxodil alone for the treatment of alopecia. In terms of the PICO framework: Population: Includes patients with any form of clinically diagnosed alopecia. Intervention: Includes using combination therapy with microneedling and minoxidil in the treatment of alopecia. Comparison: Includes comparison to minoxidil alone as control group. Outcome: Primary outcome: Increased hair density. Secondary outcome: Increased hair diameter.

Rationale: The rationale of this study is to study the efficacy of novel treatments for alopecia. Minoxidil has been commonly used as a gold standard for alopecia treatment, however, recent studies are showing the benefit of adjuvant therapy using microneedling. This study will investigate the potential benefits and associated adverse events of using this multimodality therapy.

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METHODS

Participant or population: The population of study includes patients with any form of clinically diagnosed alopecia by a physician or healthcare provider.

Intervention: Includes using combination therapy with microneedling and minoxidil in the treatment of alopecia.

Comparator: Includes comparison to minoxidil alone as control group.

Study designs to be included: Only randomized controlled studies (RCTs) will

be included in the meta-analysis and systematic review.

Eligibility criteria: These standards applied to inclusion: (1) RCTs using parallel or crossover study designs; (2) the usage of microneedling and minoxidil for the treatment of alopecia, including combination therapy, and monotherapy; (3) research done on people of any age who have been diagnosed with any kind of alopecia; (4) the study's complete text was accessible; and (5) the investigation offered reliable data that could be studied, including the total number of participants and the insightful outcomes of each metric. These standards applied to exclusion: (1) research that did not offer adequate information on results in experimental or control groups; (2) trials conducted on nonhuman subjects; (3) case studies with a total of 10 or less participants; and (4) research conducted on individuals without a medical professional's definitive alopecia diagnosis. The most recent study was included in the meta-analysis if the exact same experiment was published in several publications or at various times. Each study was included if the same team of researchers conducted numerous experiments on the same set of people.

Information sources: We conducted a sensitivity literature search (publications up to December 2022) across three different databases (Scopus, Cochrane, Embase) to find RCTs evaluating the impact of minoxidil and microneedling on hair follicle development. Additionally, we examined the National Institutes of Health's United States National Library of Medicine for active registered clinical studies. In order to find target articles, we considered Medical Subject Headings (MeSH) as well as non-MeSH phrases. The following search criteria included the main terms: "microneedling, minoxidil, and alopecia." An exhaustive list of all search terms used will be provided. If more data from the study was required, the authors were contacted. Additionally, we looked through the connected articles' references list for relevant sources.

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Main outcome(s): Primary outcome: Increased hair density. Secondary outcome: Increased hair diameter.

Additional outcome(s): Other additional outcomes include adverse events noted, photographic assessments of patients, and patient satisfaction scores.

Quality assessment / Risk of bias analysis:

Using the Cochrane Collaboration's technique for assessing risk of bias, two independent study authors will each independently determine the risk of bias for the appropriately screened studies. The possible sources of biases were identified based on the Cochrane predefined evaluation included: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases. High risk of bias, barely meeting the quality criteria and having a high risk of bias. Uncertain risk of bias, unclear about one or more quality requirements and having a moderate risk of bias. Low risk of bias, fulfilled all quality criteria and had a low risk of bias. Discussion among the researchers helped to settle any disagreements over the quality rating.

Strategy of data synthesis: RevMan (Cochrane Collaboration) will be used to evaluate the data. The difference between minoxidil and minoxidil with microneedling in treating alopecia throughout a range of time cycles (12-24 weeks) will be evaluated in terms of changes in total hair count and hair diameter, the investigator's evaluation of pictures, and adverse event assessment. Using RevMan, the mean difference will be utilized to assess continuous outcomes. and 95% confidence intervals will be used to assess similar data. If P>0.05, the indicator will be classified as a fixedeffects model; if not, a random-effects model will be applied. The I2 statistic, which will show the degree of variability across the trails, will be used to assess the consistency.

Subgroup analysis: Subgroup analysis will be conducted on varied groups. Namely groups that used the same depth of microneedling and groups with the same time frame of treatment, to ensure more consistent results. Further subgroup analysis will be identified after full review of literature.

Sensitivity analysis: When appropriate sensitivity analysis will be conducted to remove outliers of the data to evaluate the data.

Language restriction: English only.

Country(ies) involved: Canada, USA.

Keywords: Alopecia; microneedling; minoxidil.

Contributions of each author:

Author 1 - Parsa Abdi - Drafted the manuscript, conducted screening, provided statistical analysis. Email: pabedinzadeg@mun.ca Author 2 - Christian Awad - Drafted the manuscript, conducted screening.

Author 3 - Michelle Robert Anthony - Manuscript preparation and writing.

Author 4 - Christopher Farkouh - Manuscript preparation and writing.