INPLASY

INPLASY2023110112

doi: 10.37766/inplasy2023.11.0112

Received: 28 November 2023

Published: 28 November 2023

Clinical effectiveness of using Myoinositol alone compared with clomiphene citrate alone and both strategies together in conception rate in women with PCOS- A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - NA.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023110112

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 November 2023 and was last updated on 28 November 2023.

INTRODUCTION

Review question / Objective Myoinositol, a member of the B complex group of vitamins, has emerged as a potential therapeutic agent for women with PCOS. It plays a crucial role in insulin signal transduction and has been associated with improvements in insulin sensitivity, ovulation, and hormonal parameters in women with PCOS .Furthermore, it is proposed that myoinositol may enhance the efficacy of clomiphene citrate in inducing ovulation. However, the evidence on the effectiveness of myoinositol, either alone or in combination with clomiphene citrate, in improving fertility outcomes in women with PCOS is inconsistent.
Therefore, this systematic review and meta-analysis aimed to synthesize the available evidence from different clinical trials to compare the efficacy of myoinositol alone or in combination with clomiphene citrate for improving ovulation and pregnancy rates in women with PCOS.

Rationale This review sought to provide a comprehensive and updated overview of the topic, potentially contributing to evidence-based decision-making in the clinical management of women with PCOS.

Condition being studied Polycystic Ovary Syndrome (PCOS) significantly impacts reproductive health, affecting 10-15% of women of reproductive age globally. This systematic review and meta-analysis, will assess the clinical effectiveness of Myoinositol (MI) alone, Clomiphene Citrate (CC) alone, and their combined use in improving conception rates for women with PCOS. PCOS, characterized by hyperandrogenism, ovulatory dysfunction, and metabolic complications, often leads to anovulatory infertility. CC, a common treatment, has limitations due to side effects and resistance.

METHODS

Search strategy To conduct this study, a specific set of keywords will be used to help streamline the

search and ensure the retrieval of the most relevant articles as shown below. The databases that will be searched will included PubMed, PMC, and Google Scholar. These databases are chosen as they are comprehensive and widely used sources of scientific literature that include a range of peer-reviewed articles and research studies across multiple disciplines.
Database Search String
PubMed ("Myoinositol" [Title/Abstract]) AND ("Polycystic Ovary Syndrome" [Title/Abstract]) AND ("Infertility" [Title/Abstract]) AND ("2009/01/01"[PDat] : “2023/12/31"[PDat])
PMC ("Myoinositol" [All Fields]) AND ("Clomiphene Citrate" [All Fields]) AND ("PCOS" [All Fields]) AND ("Hirsutism" [All Fields]) AND ("Obesity" [All Fields]) AND ("2009/01/01"[PDat] : “2023/12/31"[PDat])
Google Scholar (allintitle: myoinositol clomiphene citrate PCOS conception regulation hirsutism obesity) AND (after: 2009) AND (before: 2024).

Participant or population The inclusion criteria for the study were women of reproductive age diagnosed with PCOS and presenting for infertility, menstrual regulation, hirsutism, or obesity. The exclusion criteria will be women presenting for infertility due to reasons other than PCOS, and those with conditions such as hypothyroidism or hyperprolactinemia.

Intervention Myoinositol, clomiphene citrate or combination.

Comparator C- Clomiphene citrate alone.

Study designs to be included Case controlled.

Eligibility criteria The inclusion criteria for the study will be women of reproductive age diagnosed with PCOS and presenting for infertility, menstrual regulation, hirsutism, or obesity. The exclusion criteria were women presenting for infertility due to reasons other than PCOS, and those with conditions such as hypothyroidism or hyperprolactinemia.

Information sources The databases that will be searched will included PubMed, PMC, and Google Scholar.

Main outcome(s) O- using combination of myoinositol and clomiphene citrate increase the pregnancy and ovulation rate.

Additional outcome(s) Additionally, the study aims to assess whether myoinositol could have secondary improvement effects on the symptoms of PCOS like Body mass index, insulin resistence.

Data management This process will be initiated with the development of a standardized data extraction form to capture all necessary information from the included studies. The form will capture details pertaining to the study design, sample size, participant characteristics, interventions and comparators, outcome measures, key findings, and any potential sources of bias. Each study will be independently assessed by two reviewers who extracted the data. The information extracted will include the authors, year of publication, study design, population characteristics (including age, body mass index, and PCOS diagnostic criteria), interventions (specifically, myoinositol and clomiphene citrate use), and outcomes (conception rate, ovulation rate, and secondary PCOS symptoms). Any discrepancies in data extraction between the two reviewers will be resolved through discussion, and if necessary, a third reviewer was consulted to reach aconsensus.

Quality assessment / Risk of bias analysis The bias assessment protocol for this systematic review will be stringently formulated and implemented using the Cochrane Collaboration's Risk of Bias 2.0 (RoB 2.0) tool. This instrument is widely recognized for its robustness in evaluating the risk of bias.

Strategy of data synthesis For each included study, the odds ratios (ORs) and their respective 95% confidence intervals (CIs) will be extracted or calculated from the reported data. These ORs will represent the odds of successful ovulation and pregnancy in the myoinositol group compared to the clomiphene citrate group. To synthesize these results, a random-effects (RE) model will be employed in the meta-analysis. The results of the meta-analysis will be visually represented through forest plots. Each plot will show the OR and 95% CI of each study as well as the pooled effect estimate and its 95% CI.

Subgroup analysis Myoinositol in comparing the ovulation rate will also be presented along with the main outcome of pregnancy rate.

Sensitivity analysis OR and 95% CI of each study as well as the pooled effect estimate and its 95% CI will be used. The heterogeneity among the included studies will be assessed using the I^2statistic.

Language restriction English.

Country(ies) involved Study will be conducted in Saudiarabia Qassim University(Nationality of authors is Pakistani).

Other relevant information NA

Keywords Infertility, Myoinositol, Polycystic ovaries, Clomiphene citrate.

Dissemination plans Will be published after completion.

Contributions of each author

Author 1 - Zaheera Saadia - Designed the study and will take part in all components including the analysis and writing of manuscript.
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Author 2 - Muhammad Munir Memon - Will be the second main reviewer of literature, will contribute in writing discussion and reviewing results.
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