INPLASY

Effectiveness and Safety of Low-Dose Naltrexone in Reducing Fibromyalgia Severity: Systematic Review and Meta-analysis

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ADMINISTRATIVE INFORMATION

Support - No financial support was received.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 August 2023 and was last updated on 25 August 2023.

INTRODUCTION

Review question / Objective This study aims to evaluate the effectiveness and safety of low-dose naltrexone in reducing pain scores and fibromyalgia severity scores in patients with fibromyalgia through an extensive systematic review and Meta-analysis of previous studies.

Rationale This systematic review and meta-analysis was conducted due to the increasing number of conflicting evidence supporting the efficacy and safety of low-dose naltrexone in managing patients with fibromyalgia. Our study excluded case reports, case series, and chart reviews and included clinical trials and observational studies to achieve substantial quality objective evidence.

Condition being studied Fibromyalgia syndrome.

METHODS

Search strategy Electronic databases and gray literature were comprehensively searched using a combination of Boolean operators and truncation for the following search terms: SCOPUS: (ALL (fibromyalgia) OR ALL (fibrositis) OR TITLE (fibromyalgia OR fibrositis) OR TITLE (fibrosi* OR *myalgia*)) AND (ALL (ldn) OR TITLE (low-dose AND naltrexone) OR TITLE ("Low-dose naltrexone") OR TITLE ("naltrexone") OR TITLE-ABS-KEY ("Low dose naltrexone") OR TITLE-ABS-KEY (naltrexone) OR TITLE-ABS-KEY (ldn) OR ALL ("Low$dose naltrexone")). PUBMED: ((fibromyalgia) OR (Fibrositis) OR ("Fibrositic nodul*") OR ("Fibrositis syndrome") OR (myalgia AND fibro)) AND ((low-dose naltrexone) OR (LDN) OR (Naltrexone)). EMBASE: ('fibromyalgia'/exp OR 'fibromyalgia' OR 'fibrositic nodule' OR 'fibrositis' OR 'fibrositis syndrome' OR 'myalgia, fibro') AND (('low-dose naltrexone') OR (ldn) OR ('naltrexone')). COCHRANE: ((("fibromyalgia"):ti,ab,kw) OR

((fibrositis):ti,ab,kw) OR ((myalgia):ti,ab,kw)) AND (((Low dosenaltrexone):ti,ab,kw) OR ((Low-dose naltrexone):ti,ab,kw) OR ((naltrexone):ti,ab,kw) OR ((LDN):ti,ab,kw)). For ProQuest and Clinicaltrials.gov, we used the terms "Fibromyalgia", "Fibrositis", "Naltrexone", and "Low-dose naltrexone". An additional Google Scholar search was conducted in August 2023.

Participant or population Individuals diagnosed with fibromyalgia syndrome.

Intervention Low-dose naltrexone (≤10mg of Naltrexone).

Comparator Placebo or standard of care.

Study designs to be included Clinical trials and observational studies with either quantitative or qualitative methodology. Systematic reviews and meta-analyses, chart reviews, case series and reports, opinion articles, duplicate articles, pre-clinical studies, guidelines, reviews, studies without outcomes of interest, and studies with valid data that cannot be extracted or calculated were excluded to achieve substantial quality of evidence.

Eligibility criteria Qualitative and quantitative methodological clinical trials and observational studies performed in humans diagnosed with fibromyalgia that used low-dose naltrexone ((≤10mg of Naltrexone) as an intervention compared to placebo or other standard of care from the inception of the database till the date the search was conducted. Studies available as conference abstracts or full text, published or unpublished and available in English were included. Only studies that evaluated change in pain score or fibromyalgia severity syndrome or both as outcomes of interest were included.

Information sources The electronic database search was performed from March through August 2023. Electronic database (PubMed, Embase, Scopus, Cochrane Library) and gray literature (ProQuest, Clinicaltrial.gov) search from inception to August 2023 was performed using the following search terms: "Fibromyalgia", "Fibrositis", "Naltrexone", and "Low-dose naltrexone".

Main outcome(s) In the meta-analyses, we evaluated the change in mean pain score and change in fibromyalgia symptoms severity scores in individuals with fibromyalgia syndrome.

Additional outcome(s) Not applicable.

Data management Zotero reference manager was using in managing the studies included in this systematic review and meta-analysis.

Quality assessment / Risk of bias analysis The database search was conducted by AO and OM, and a consensus between the two authors resolved disagreement about the study selection and data extraction. Quality assessment of eligible studies was performed using the Cochrane Risk of Bias tool for clinical trials and the Newcastle-Ottawa scale for Observational studies. The bibliographies of included studies were also reviewed for any missing studies.

Strategy of data synthesis AO performed data abstraction on eligible studies using a data extraction form with the following details: title, authors, publication date, study design, study objective(s), participants, intervention, and outcome of interest, and how the outcome was measured.

Subgroup analysis Not applicable.

Sensitivity analysis Sensitivity analysis of full-text studies (excluding conference abstracts without full-texts) and sensitivity analysis by study design (clinical trials versus observational studies) were carried out.

Language restriction English language studies only.

Country(ies) involved The authors are American or Nigerian.

Keywords Fibromyalgia; pain; Low-dose naltrexone; naltrexone; systematic review; meta-analysis.

Contributions of each author

Author 1- Abiodun Ologunowa – Database search, Data abstraction, analysis, draft preparation.
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