INPLASY

Efcacy and safety of elagolix in moderate to severe endometriosis associated pain: a systematic review and meta analysis

INPLASY202390029

doi: 10.37766/inplasy2023.9.0029

Received: 10 September 2023

Published: 10 September 2023

Corresponding author:
Wei Wei

472606614@qq.com

Author Affiliation:
People's Hospital of Zhongjiang County.

Liu, JF[1]; Wei, W[2]; Zhang, Y[3]; Chang, E[4]; Hou, Y[5]; Wei, X[6]; Yue, X[7]; Zhong, L[8].

ADMINISTRATIVE INFORMATION

Support - Deyang Science and Technology Plan Project.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202390029

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 September 2023 and was last updated on 10 September 2023.

INTRODUCTION

Review question / Objective The aim of this study is to comprehensively analyze evidence of elagolix in the treatment of moderateto-severe endometriosis-associated pain.

Condition being studied Endometriosis-related pain, such as dysmenorrhea, non-menstrual pelvic pain, and difficulties with sexual intercourse, severely impairs the physical and mental health of patients and imposes a heavy economic burden. Elagolix is an oral GnRH antagonist that has been approved by the FDA for the treatment of endometriosis. It inhibits the secretion of estrogen in a dose-dependent manner and allows for a rapid reversal of estrogen suppression shortly after discontinuation. Therefore, it can be conveniently dosed to balance effectiveness and safety.

METHODS

Search strategy Search: (((((Elagolix[Title/Abstract]) OR (R-(+)-4-(2-(5-(2-fluoro-3-methoxyphenyl)-3-(2-fluoro-6-(trifluoromethyl)benzyl)-4-methyl-2,6-dioxo-3,6-dihydro-2H-pyrimidin-1-yl)-1-phenylethylamino)butyrate[Title/Abstract])) OR (elagolix sodium[Title/Abstract])) OR (Orilissa[Title/Abstract])) AND ((((Endometriosis[Title/Abstract]) OR (Endometrioses[Title/Abstract])) OR (Endometrioma[Title/Abstract])) OR (Endometriomas[Title/Abstract]))) AND ((randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR clinical trials as topic[mesh:noexp] OR randomly[tiab] OR trial[ti]) NOT (animals [mh] NOT (humans [mh] AND animals[mh]))).

Participant or population Patients with endometriosis.

Intervention Elagolix.

Comparator Placebo.

Study designs to be included Randomized controlled trials (RCTs) with unlimited languages.

Eligibility criteria Endometriosis is characterized by the presence and growth of endometrial tissue in locations other than the uterine cavity. While a definitive diagnosis should be made histologically, alternative diagnostic methods, such as laparoscopy are performed. The American Society of Reproductive Medicine (ASRM) staging system has become the most common and international system, and diagnosis based on laparoscopic findings has been recognized as the standard. However, laparoscopic findings have various limitations and flaws and therefore cannot necessarily serve as a perfect alternative to histological diagnoses. Ultrasonography and magnetic resonance imaging (MRI) have later been incorporated into the diagnosis of endometriosis. As diagnostic imaging has improved in quality, invasive laparoscopic diagnosis has somewhat diminished in relative value, and the exclusive use of laparoscopy for diagnosis has become much less common. Subjective and objective findings and biochemical tests are all useful only when combined with the results of diagnostic imaging and laparoscopy; none are used separately for diagnosis.

Information sources Pubmed, Embase, cochrane, web of science, CBM, CNKI, wanfang, ClinicalTrials.

Main outcome(s) Change from baseline to month 3 in number rating scale (NRS) scores; Change from baseline to month 3 in dyspareunia (DYSP); Change from baseline to month 3 in non-menstrual pelvic pain (NMPP); Patient Global Impression of Change Scale.

Quality assessment / Risk of bias analysis The quality assessment for randomized controlled trials was conducted by the Cochrane Risk of Bias tool 1. Two reviewers will independently assess the risk of bias based on the following five domains: random sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; blinding of outcome data; selective reporting; and other bias.

Strategy of data synthesis For dichotomous data, the results were expressed as RR with 95% confidence intervals. For continuous data, the results were pooled for meta-analysis as the mean difference (MD) with 95% confidence intervals if all studies reported the same scales. When data were reported on different methods or scales, the standardized mean difference (SMD) was calculated. $P < 0.05$ represented statistical significance.

Subgroup analysis The effectiveness and safety of Elagolix are analyzed in subgroups based on dosage, including 150mg once daily (qd), 250mg once daily (qd), and 200mg twice daily (bid).

Sensitivity analysis Stata software is used to perform sensitivity analysis, reflecting the sensitivity of the article by examining how the effect size changes after removing a particular study.

Country(ies) involved China.

Keywords elagolix; Endometriosis.

Contributions of each author

Author 1 - Jinfeng Liu.
Email: 472606614@qq.com
Author 2 - Wei Wei.
Email: weiweieric0405@163.com
Author 3 - Yue Zhang.
Author 4 - En Chang.
Author 5 - Yi Hou.
Author 6 - Xi Wei.
Author 7 - Xin Yue.
Author 8 - Li Zhong.