INPLASY PROTOCOL

To cite: Chen et al. Association analysis between vitamin D level and depression in women perimenopause: A protocol of systematic review and meta-analysis. Inplasy protocol 202040117. doi: 10.37766/inplasy2020.4.0117

Received: 19 April 2020

Published: 19 April 2020

Corresponding author:
Jie Chen

Yuanjie8782@163.com

Author Affiliation:
Shaanxi Provincial Hospital of Traditional Chinese

Support: **Yes.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None.

Association analysis between vitamin D level and depression in women perimenopause: A protocol of systematic review and meta-analysis

Chen J[1]; Yuan J[2].

Review question / Objective: **Does vitamin D level is related to the occurrence of depression in perimenopausal women?**
Condition being studied: **In recent decades, many researches manifested that the perimenopause is a window of vulnerability for the development of both depressive symptoms and major depressive episodes. Some scholar thought that those women diagnosed with depression may be particularly sensitive to changes in the hormonal milieu experienced premenstrual, during the postpartum period or during the menopause transition in. Risk factors for depressive symptoms during the perimenopause include prior MDD, psychosocial factors, anxiety symptoms, and reproductive-related mood disturbance. However, active vitamin-D, exerts protective and regulatory effects on the brain dopamine system and suggests that similar to the antidepressant. Therefore, serum 25(OH)D level may be negatively correlated with the perimenopausal depression.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 April 2020 and was last updated on 19 April 2020 (registration number INPLASY202040117).

INTRODUCTION

Review question / Objective: **Does vitamin D level is related to the occurrence of depression in perimenopausal women?**

Condition being studied: **In recent decades, many researches manifested that the perimenopause is a window of vulnerability for the development of both depressive symptoms and major depressive episodes. Some scholar thought that those women diagnosed with depression may be particularly sensitive to changes in the hormonal milieu experienced premenstrual, during the postpartum period or during the menopause transition in. Risk factors for depressive symptoms during the**

perimenopause include prior MDD, psychosocial factors, anxiety symptoms, and reproductive-related mood disturbance. However, active vitamin-D, exerts protective and regulatory effects on the brain dopamine system and suggests that similar to the antidepressant. Therefore, serum 25(OH)D level may be negatively correlated with the perimenopausal depression.

METHODS

Search strategy: We will retrieve each database from the built-in until October 2020.The English literature mainly searches Cochrane Library, Pubmed, EMBASE, and Web of Science. While the Chinese literature comes from CNKI, CBM, VIP and Wangfang database. We adopt the combination of heading terms and free words as search strategy which decided by all the reviewers. Search terms: serum vitamin D level, vitamin D, 25(OH)D, VD, 1,25 (OH) 2D3, vitamin D deficiency, vitamin D supplementation, postmenopausal depression, depression in menopausal women, perimenopausal depression, menopause depression. At the same time, we will retrieve other resources to complete the deficiencies of the electronic databases, mainly searching for the clinical trial registries and grey literature about vitamin D level and depression in women before and after menopause on the corresponding website.

Participant or population: Patients with clinically diagnosed perimenopausal depression.

Intervention: Women depression in perimenopause with low serum vitamin D.

Comparator: Women depression in perimenopause with normal serum vitamin D.

Study designs to be included: Clinical randomized controlled trials (RCTs).

Eligibility criteria: The study only selects clinical randomized controlled trials of vitamin D level for perimenopausal depression published in both Chinese and English. However, animal experiments, reviews, case reports and non-randomized controlled trials are excluded.

Information sources: We will retrieve each database from the built-in until October 2020.The English literature mainly searches Cochrane Library, Pubmed, EMBASE, and Web of Science. While the Chinese literature comes from CNKI, CBM, VIP and Wangfang database. We adopt the combination of heading terms and free words as search strategy which decided by all the reviewers. Search terms: serum vitamin D level, vitamin D, 25(OH)D, VD, 1,25 (OH) 2D3, vitamin D deficiency, vitamin D supplementation, postmenopausal depression, depression in menopausal women, perimenopausal depression, menopause depression. At the same time, we will retrieve other resources to complete the deficiencies of the electronic databases, mainly searching for the clinical trial registries and grey literature about vitamin D level and depression in women before and after menopause on the corresponding website.

Main outcome(s): The primary outcomes include serum vitamin D level, Hamilton Depression Scal(HAMD) or Beck Depression Inventory (BDI) or Zung's Self-rating Depression Scale (SDS) or Patient Health Questionnare-9(PHQ-9).

Additional outcome(s): Insomnia severity index(ISI) or Pittsburgh sleep quality index(PSQI) or Hamilton anxiety scale (HAMA), FSH levels and history of menstrual irregularity, serum estradiol measurements.

Quality assessment / Risk of bias analysis: The quality assessment of RCTs adopts the risk of bias (ROB) assessment tool provided by the Cochrane Handbook. The following seven items, such as random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data,

selective outcome reporting, and other bias, are evaluated by three grades of "low bias", "high bias" and "unclear bias". The discrepancies will get a consistent conclusion by discussing between both reviewers or seeking the third-party consultation.

Strategy of data synthesis: Review Manager software version 5.3 provided by the Cochrane Collaboration will be performed for data synthesis and analysis. The dichotomous data is represented by RR, continuous data is expressed by MD or SMD. If there is no heterogeneity (I20.1), the data is synthesized using a fixed effect model. Otherwise (I2≥50%, P＜0.1), a random effect model is used to analyze. Then subgroup analysis will be conducted basing on the different causes of heterogeneity. If a meta- analysis cannot be performed, it will be replaced by a general descriptive analysis.

Subgroup analysis: If the results of the study are heterogeneous, we will conduct a subgroup analysis for different reasons. Heterogeneity is manifested in the following several aspects, such as race, age, gender, different intervention forms, pharmaceutical dosage, treatment course.

Sensibility analysis: Sensitivity analysis is mainly used to evaluate the robustness of the primary outcome measures. The method is that removing the low-level quality study one by one and then merge the data to assess the impact of sample size, study quality, statistical method, and missing data on results of meta-analysis.

Language: English.

Country(ies) involved: China.

Keywords: Perimenopausal depression; vitamin D lever; meta-analysis; protocol..