INPLASY PROTOCOL

To cite: Chen et al. Vitamin D supplementation in the treatment of type 2 diabetic microangiopathy: a protocol for a systematic review and meta-analysis. Inplasy protocol 202050055. doi: 10.37766/inplasy2020.5.0055

Received: 13 May 2020

Published: 14 May 2020

Corresponding author:
Junmin Chen

1335085129@qq.com

Author Affiliation:
Hospital of Chengdu University of TCM

Support: **Sichuan the Science and Technology Program of Sichuan Province in 2019**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None.

Vitamin D supplementation in the treatment of type 2 diabetic microangiopathy: a protocol for a systematic review and meta-analysis

Chen, JM[1]; Gong, XY[2]; Liu, J[3]; Wang, TT[4]; Shi, XY[5]; Zhang, XR[6]; Chen, Q[7].

Review question / Objective: **How effective is vitamin D supplementation in the treatment of type 2 diabetic microangiopathy?**
Condition being studied: **Vitamin D. Microangiopathy of type 2 diabetes mellitus.**
Information sources: **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.Simultaneously we will retrieval clinical registration tests and grey literatures.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 May 2020 and was last updated on 14 May 2020 (registration number INPLASY202050055).

INTRODUCTION

Review question / Objective: **How effective is vitamin D supplementation in the treatment of type 2 diabetic microangiopathy?**

Condition being studied: **Vitamin D. Microangiopathy of type 2 diabetes mellitus.**

METHODS

Search strategy: We will search each database from the built-in until March 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.Simultaneously we will retrieval clinical registration tests and grey literatures.

Participant or population: Inclusion: The patients met the diagnostic criteria of T2DM proposed by the American Diabetes Association (ADA) in 2010, regardless of race, gender and age.Diabetic microangiopathy of different degree. Exclusion:Neuropathy caused by other causes and patients with a history of serious heart disease, liver and kidney dysfunction, mental illness or related drug allergy.

Intervention: This meta-analysis will include the RCTs of vitamin D supplementation regardless of dose and frequency. Trials with a minimum treatment duration of at least 4 weeks will be included.

Comparator: This meta-analysis will include the RCTs that administered with placebo, that with no treatment or active pharmacological treatment (regardless of dose, frequency).Trials with a minimum treatment duration of at least 4 weeks will be included.

Study designs to be included: We will include randomised trials to assess the beneficial effects of the treatments, and will supplement these with observational studies.

Eligibility criteria: The patients met the diagnostic criteria of T2DM proposed by the American Diabetes Association (ADA) in 2010, regardless of race, gender and age.Diabetic microangiopathy of different degree.

Information sources: 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.Simultaneously we will retrieval clinical registration tests and grey literatures.

Main outcome(s): Patient before and after treatment: markedly effective: symptoms improved significantly >70%; effective: symptoms reduced by 30% to 70%; ineffective: symptom improvement is <30% or no improvement, or even worse. The nerve conduction velocity includes the sensory nerve conduction velocity and the motor nerve conduction velocity, which are evaluated by electromyography.In addition, urinary microalbumin / creatinine and fundus photography are also included.

Additional outcome(s): Secondary outcomes included fasting blood glucose and glycosylated hemoglobin, glomerular filtration rate, creatinine, uric acid and adverse events.

Quality assessment / Risk of bias analysis: Assessing the risk of bias in studies. In this tool, the risk of bias of a trial is assessed through 7 items: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting(reporting bias), other bias. Each item is classified as "Low risk","High risk" or "Unclear risk". Two reviewers will conduct the risk of bias assessment independently and any disagreements will be solved by a discussion of all reviewers.

Strategy of data synthesis: Substantial when P50%. If P>.05 and I^2<50%, then the studies included is homogeneous and the differences between them can be ignored. If there is significant heterogeneity, the random effect model will used to pool data, and if there is no significant heterogeneity, then the fixed effect model will be used. If quantitative synthesis is not appropriate due to substantial heterogeneity, then the results will be presented with tables and figures.

Subgroup analysis: Substantial when P50%. If P>.05 and I^2<50%, then the studies included is homogeneous and the differences between them can be ignored. If there is significant heterogeneity, the random effect model will used to pool data, and if there is no significant heterogeneity, then the fixed effect model will be used. If quantitative synthesis is not appropriate due to substantial heterogeneity, then the results will be presented with tables and figures.

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 metaanalysis.

Language: English.

Country(ies) involved: China.

Keywords: vitamin D; type 2 diabetic microangiopathy; protocol; systematic review; meta-analysis

Contributions of each author:
Author 1 - Junmin Chen.
Author 2 - Xiayu Gong.
Author 3 - Jie Liu.
Author 4 - Tingting Wang.
Author 5 - Xiaoyan Shi.
Author 6 - Xiaoran Zhang.
Author 7 - Qiu Chen.