International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Topical phenytoin use in diabetes related foot ulcers

INPLASY202410023

doi: 10.37766/inplasy2024.1.0023

Received: 07 January 2024

Published: 07 January 2024

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ADMINISTRATIVE INFORMATION

Support - Nil.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202410023

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 January 2024 and was last updated on 07 January 2024.

INTRODUCTION

Review question / Objective What is the effect of the use of topical phenytoin in the healing of diabetes related foot ulcers compared to the standard of care or other dressings?

Rationale Phenytoin in its oral formulation has been used as an anti-epileptic medication since the 1930s. One of its adverse effects was gingival hypertrophy, recognized in 1938. This then led to further investigations – as the gingival tissue proliferation might represent a signal that phenytoin could increase tissue production locally in wounds and thereby promoting healing. Topical phenytoin is currently not recommended for use in DFU management by national or international guidelines. We want to conduct a systematic review of all the randomised trials looking at topical phenytoin and diabetes related foot ulcers. Prior systematic reviews in this area did not include all the studies.

Condition being studied Diabetes related foot ulcers.

METHODS

Search strategy Search terms: Diabetes/Diabetic + Phenytoin + Ulcer/wound + RCT filter Databases included: MEDLINE, EMBASE, CENTRAL, Google Scholar, Clinicaltrials.gov.

Participant or population Patients with diabetes related foot ulcers.

Intervention Topical phenytoin.

Comparator Usual care/other dressing.

Study designs to be included Randomised controlled trials.

Eligibility criteria Only RCTs done for Diabetic foot ulcers will be included.

Information sources As above, if needed individual authors may be contacted.

Main outcome(s) All healing related outcomes will be included. Other outcomes – such as quality of life, health economic outcomes will not be included.

Quality assessment / Risk of bias analysis Quality assessment/Risk of bias analysis will be conducted using the RoB2 tool by 2 authors independently.

Strategy of data synthesis Data collection: Once studies from the above data bases are identified, duplicates will be removed. The remaining studies will enter the screening phase. Two reviewers will work independently to screen the studies for the 'assessment of eligibility' phase. Any discrepancies will be resolved by involving a third author. All studies deemed eligible will be further evaluated by screening their full text. Those deemed eligible will be included in the final review. If applicable, data extraction for meta-analysis will be performed using standardised forms. The included studies will be assessed for bias using the Cochrane's risk of bias tool.

Subgroup analysis Nil subgroups are planned a priori.

Sensitivity analysis Nil a priori sensitivity analyses are planned. If there are specific issues identifies due to the individual peculiarities of the data set then sensitivity analyses will be performed and reported.

Language restriction Only English language publications will be included.

Country(ies) involved United Kingdom.

Other relevant information Co-first-authorship for the 1st two authors is planned when submission for dissemination.

Keywords Phenytoin, Foot Ulcer, Diabetic.

Dissemination plans The findings of this study will be presented in the form of a journal article, and if applicable to conferences.

Contributions of each author

Author 1 - Charles Barry - Contributions: substantial contributions to the design; data acquisition and interpretation, drafting and final approval of the document, and accountable for accuracy of the submission.
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Author 2 - Mohamed Shefan Hameed - Contributions: substantial contributions to the design; data acquisition and interpretation, drafting and final approval of the document, and accountable for accuracy of the submission.
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