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N/A.

ADMINISTRATIVE INFORMATION

Support - Nil.

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202560049

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 June 2025 and was last updated on 11 June 2025.

INTRODUCTION

Review question / Objective Does taking oral isotretinoin have an effect on patient's serum thyroid parameters?

Rationale Isotretinoin has been used in the treatment of acne vulgaris and other follicular occlusion disorders since the 1970s. Its mechanism of action remains incompletely understood but is thought to be mediated through effects on sebum production, hyperkeratinization, inflammation, and Cutibacterium acnes. It has been postulated that one of the ways in which isotretinoin may help to treat acne is by suppressing pituitary hormone levels. In addition to sex hormones, acne severity has been associated with hypothyroidism and autoimmune thyroiditis. Isotretinoin has been shown to induce changes in the levels of thyroid hormones and antibodies in patients with acne vulgaris but the data remains limited and conflicting.

Condition being studied Isotretinoin use

Serum thyroid parameters (e.g. thyroid-stimulating hormone, thyroxine, triiodothyronine, thyroid antibodies).

METHODS

Search strategy Search terms:
Isotretinoin OR Roaccutane OR Accutane OR 13-cis-retinoic acid
AND thyroid hormone OR thyroid-stimulating hormone OR thyroxine OR triiodothyronine OR thyroid antibodies OR thyroglobulin antibodies OR thyroid peroxidase antibodies OR thyroid-stimulating hormone receptor antibodies OR thyrotropin receptor antibodies

Databases: PubMed, Europe PMC, Scopus, Embase.

Participant or population Patients taking isotretinoin who had at least two sets of blood tests for thyroid parameters.

Intervention Use of oral isotretinoin.

Comparator N/A.

Study designs to be included Cohort and case-control.

Eligibility criteria Patients taking isotretinoin who had testing for serum thyroid parameters.

Information sources Electronic databases.

Main outcome(s)

thyroid-stimulating hormone

thyroxine

triiodothyronine

thyroid antibodies.

Additional outcome(s) N/A.

Data management

After extraction, relevant data from eligible studies will be recorded in microsoft excel

The excel file will be encrypted and kept on a password-protected laptop computer.

Quality assessment / Risk of bias analysis NIH quality assessment tool.

Strategy of data synthesis Data collection will be performed independently by two authors with any disagreements regarding inclusion of the citations being referred to a third author for mediation. Information will be collected using a standardised data collection form with the principal outcomes of interest being the levels of serum thyroid parameters. If data from individual patients is unavailable, the aggregate data, including average change and statistical analyses of the significance of change will be collected. Potential sources of bias in the identified studies, including the small patient cohorts, the variability in diagnostic assessments, and lack of control populations will be acknowledged. Bias will also be assessed using the NIH quality assessment tool.

Statistical analyses will be performed with RStudio 4.3.1 (RStudio: Integrated Development for R. RStudio, PBC, Boston, MA URL <http://www.rstudio.com/>) using packages meta 6.5-0 (Schwarzer, 2023) and dmetar (Harrer et al. 2019). Meta-analysis will be performed with metaprop function and presented as a Forest plot. A Funnel plot will be constructed to make a visual representation assessing whether small-study effects are present. Linear regression and Egger's tests will then be used to quantitatively assess for plot asymmetry.

Subgroup analysis N/A.

Sensitivity analysis N/A.

Language restriction English.

Country(ies) involved Australia.

Other relevant information N/A

Keywords Isotretinoin, thyroid hormones, thyroid-stimulating hormone, thyroxine, triiodothyronine, thyroid antibodies.

Dissemination plans

Publication in medical journal

Presentation as abstract at medical conference.

Contributions of each author

Author 1 - Joshua Farrell - Literature review; Data extraction; Data analysis; Risk of bias assessment; Writing manuscript.

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Author 2 - Thomas Stewart - Literature review; Data extraction; Data analysis; Risk of bias assessment; Writing manuscript.

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