PROSPERO International prospective register of systematic reviews

Clinical, behavioural and pharmacogenomic factors influencing the response to levothyroxine therapy in patients with diagnosed primary hypothyroidism

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Citation

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Review question(s)

To what extent do clinical, behavioural and pharmacogenomic factors affect the response to levothyroxine therapy in patients with primary hypothyroidism?

Searches

The following databases will be searched: Web of Science, MEDLINE (Ovid) and PubMed.

Any publication period will be used, and language will be restricted to English only. Articles will also be identified from reference lists.

Types of study to be included

All potential studies will be initially accepted; RCTs, case studies, observational studies, retrospective audits etc.

Condition or domain being studied

Overt or subclinical hypothyroidism and TSH levels

Participants/ population

Inclusion criteria: Adults aged 18 or older, with history of hypothyroidism and receiving levothyroxine treatment.

Exclusion criteria: Children (aged less than 18 years), patients on other forms of hormone replacement therapy or combination therapy, pregnant women, patients with secondary hypothyroidism, patients previously treated for hyperthyroidism.

Intervention(s), exposure(s)

Clinical, behavioural and pharmacogenomic interventions. Any intensity and frequency with length of intervention greater than 6 weeks.

Comparator(s)/ control

A control or comparative group is necessary. This can be placebo/no treatment/standard therapy/ usual care/ alternative treatment.

Outcome(s)

Primary outcomes

The quantitative effect of clinical/ behavioural/pharmacogenomic factors on TSH levels.

Secondary outcomes

Effects on T4 and T3 levels, any short term effects, mortality, morbidity, quality of life, treatment complications, adverse effects, physical functioning, social functioning.

Data extraction, (selection and coding)

Studies will be screened through reading the title, abstract and then full text. Two reviewers will independently participate in the extraction of data and the selection of articles. If there is disagreement between the reviewers, a third reviewer will be consulted.

The following data will be extracted from articles that meet the inclusion criteria:

1) Authors, year of publication, country, study design, number of patients

2) Population demographics

3) Reason for hypothyroidism

4) Co-morbidities

5) Levothyroxine dose – range/average

6) TSH levels

7) Intervention; type, duration etc.

Risk of bias (quality) assessment
Articles will be assessed referring to the GRADE guidelines. Two reviewers will assess articles for quality to reduce bias. Any disagreement will be resolved by consulting with a third reviewer.

Strategy for data synthesis
A four-phase flow diagram will be created depicting the search strategy used during the review, and the numbers of articles excluded and included, and on what basis (PRISMA). A combined narrative synthesis of the findings from the included studies will be provide. A summary of the difference between the mean TSH levels of patients from various interventions will be presented. A summary of the effect of various attributes affecting TSH control will be presented. Descriptive summary tables will also be created.

Analysis of subgroups or subsets
None planned

Dissemination plans
Findings will be disseminated at conferences and in professional and peer-reviewed journals.

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06 June 2016

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Not applicable

Conflicts of interest
None known

Language
English

Country
England, Wales

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Humans; Hypothyroidism; Pharmacogenetics; Thyrotropin; Thyroxine

Stage of review
Ongoing

Date of registration in PROSPERO
15 December 2015

Date of publication of this revision
15 December 2015

Stage of review at time of this submission	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No