

Does treatment with naltrexone (a medication) improve quality of life in patients with hypothyroidism (underactive thyroid)?

ACTRN12625000131459

Status	RECRUITING
Phase	Phase 2
Sponsor	St. Vincent's Hospital, Sydney
Enrollment	150 participants

Plain Language Summary

Hypothyroidism — an underactive thyroid — is usually treated with thyroxine tablets that replace the missing hormone. But many people still feel unwell even when their blood tests look perfectly normal. They may experience fatigue, brain fog, weight problems, or low mood. Currently, there are no other approved medications specifically for this situation.

This study is testing whether a low dose of naltrexone — a medication normally used for alcohol and opioid dependence — can help people with Hashimoto's-related hypothyroidism feel better when added to their usual thyroxine treatment. Participants will receive either naltrexone or an identical-looking placebo tablet and will be assessed for improvements in quality of life, symptoms, and various health measures over the course of the study.

You may be eligible if you are 18 or older, have been diagnosed with Hashimoto's disease for more than 3 months, have been on a stable thyroxine dose for at least 3 months, and still feel that your treatment isn't working well enough. People who are pregnant, planning pregnancy, have an opioid dependency, or have recently changed their diet or other medications are not eligible.

Key Eligibility Criteria

Inclusion (7)

- Age greater of equal to 18-years.
- Greater than 3 months since diagnosis of Hashimoto's disease.
- Stable thyroxine dose for greater or equal to 3 months.
- Thyroid stimulating hormone (TSH) level within normal range.
- Dissatisfaction with thyroxine treatment.

... and 2 more (see full listing online)

Exclusion (4)

- Documented allergy to naltrexone.
- Opioid dependence or inability to abstain from opioids during the study.
- Recent modification (within 3-months) of diet, lifestyle or medication known to impact weight, blood pressure, thyroid function or other important study outcome measures.
- Pregnancy or planning pregnancy.

Locations (1 total)

NSW, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12625000131459>

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