

Trial of mycophenolate for persistent symptoms of hypothyroidism

Submission date 16/05/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/07/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/10/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The TRIUMPH trial is investigating whether a drug called mycophenolate mofetil can help women aged 18 to 50 with an underactive thyroid who continue to experience symptoms such as tiredness, lethargy, weight issues, aches and pains and 'brain fog'. The study is exploring whether ongoing inflammation in the thyroid might be causing these symptoms and if mycophenolate mofetil can help reduce the inflammation and help patients feel better.

Who can participate?

Female patients with Hashimoto thyroiditis aged 18 - 50 years.

What does the study involve?

Participants will be randomly allocated to take either mycophenolate mofetil or placebo (a 'dummy' treatment) tablets. A total of 48 people will join the trial. Most will get the drug mycophenolate (30 people), and 18 will get a placebo (a dummy pill). You will take a tablet twice a day for four months. Neither you nor your doctors will know which treatment you are getting until the trial is finished.

What are the possible benefits and risks of participating?

Mycophenolate mofetil is used to treat many inflammatory and immune-related conditions like arthritis and autoimmune liver disease. It has not been used in people with Hashimoto's Thyroiditis before, but it has been safely used for over 25 years.

Where is the study run from?

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

May 2025 to April 2028

Who is funding the study?

Medical Research Council (UK)

Who is the main contact?
Triumph@newcastle.ac.uk

Contact information

Type(s)

Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1010665

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

10785, CPMS 65473

Study information

Scientific Title

Trial of Mycophenolate for Persistent symptoms of Hypothyroidism

Acronym

TRIUMPH

Study objectives

Primary objective:

Determine whether MMF treatment can reduce thyroid inflammation in patients with Hashimoto thyroiditis

Secondary objectives:

1. Determine whether MMF treatment can ameliorate symptoms of hypothyroidism and improve wellbeing.
2. Determine whether changes in thyroid inflammation correlate with changes in symptoms and wellbeing.
3. Determine whether MMF treatment can reduce thyroid lymphocyte metabolic activity as judged by nuclide (FDG-PET) imaging in patients with Hashimoto thyroiditis.
4. Determine whether MMF treatment changes serum markers of inflammation in Hashimoto thyroiditis patients.
5. Determine whether MMF treatment is associated with change in other inflammatory cell populations (including CD4, CD8, CD19, CD56 positive lymphocytes) in Hashimoto's thyroiditis patients.
6. Determine whether MMF treatment changes serum thyroid hormones.
7. Determine whether MMF treatment can change cognitive function.
8. Determine whether changes in serum inflammatory markers are associated with changes in symptoms and wellbeing.
9. Determine if MMF is safe in this patient group.
10. Consider the long-term effect of MMF on quality of life.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 15/07/2025, East Midlands - Nottingham 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8009; nottingham2rec@hra.nhs.uk), ref: 25/EM/0124

Study design

Interventional double blind randomized parallel group placebo controlled trial

Primary study design

Interventional

Study type(s)

Efficacy, Safety

Health condition(s) or problem(s) studied

Hashimoto's Thyroiditis

Interventions

Participants are randomised using an online system to receive either Mycophenolate Mofetil (MMF) tablets or matched placebo ("dummy" tablets). Participants will be randomised in a 5:3 ratio (30 participants to MMF and 18 to placebo). Participants will take a tablet orally twice daily, one in the morning and one in the evening. Participants will take trial treatment for 16 weeks and will be followed up until 22 weeks.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Mycophenolate mofetil Tillomed 500 mg film-coated tablets

Primary outcome(s)

Change in numbers of CD45+ thyroid lymphocytes assayed by flow cytometry (baseline to 16 weeks) assayed from thyroid cellular aspirates

Key secondary outcome(s)

1. Change in FACIT-F, ThyPRO39, SF-36, GHQ-12, and POMS2 scores (baseline to 8 and 16 weeks).
2. Correlation of changes in FACIT-F, ThyPRO39, SF-36, GHQ-12, and POMS2 scores with changes in the number of thyroid lymphocytes (baseline to 16 weeks).
3. Change in thyroid SUVmax during 18FDG-FDG PET/CT scanning (baseline to 16 weeks).
4. Change in serum TPOAb, TgAb, hsCRP, procalcitonin, ESR, and neutrophil-to-lymphocyte ratio (baseline to 8 and 16 weeks).
5. Change in numbers of CD4, CD8, CD19, and other thyroid lymphocyte subsets assayed by flow cytometry (baseline to 16 weeks).
6. Change in TSH, FT4, and FT3 (baseline to 8 and 16 weeks).
7. Change in cognitive function tests: digit-span, trail making, complex figure, and pinboard tests (baseline to 8 and 16 weeks).
8. Correlation of changes in FACIT-F, ThyPRO39, SF-36, GHQ-12, PSQI, POMS2, and WHO-5 scores with serum TPOAb, hsCRP, and other inflammatory markers (baseline to 16 weeks).
9. Change in serum liver function and blood count parameters (baseline to 8 and 16 weeks).
10. Adverse reactions up to 16 weeks.
11. Change in Levothyroxine dose.
12. Change in FACIT-F score at week 22.

Completion date

30/04/2028

Eligibility

Key inclusion criteria

1. Female patients ≥ 18 yrs and ≤ 50 yrs old
2. Hashimoto thyroiditis with at least one documented serum TSH ≥ 7.0 mU/L
3. Current positive thyroid peroxidase antibodies (TPOAb ≥ 34 U/L)
4. Serum TSH currently within reference range
5. On stable dose of levothyroxine for at least 3 months
6. Persistent fatigue as judged FACIT-F score ≥ 7 and ≤ 35
7. For women of child-bearing potential (WOCBP), willing to use a highly effective contraceptive

method during their participation in the trial

8. Able to understand and complete trial procedures (with translation or verbal explanation if required).

9. Willing and able to provide informed consent prior to any trial procedures taking place

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

Female

Key exclusion criteria

1. Previous thyroidectomy or radioiodine treatment
2. Pregnant or breastfeeding, or with a plan for pregnancy within 6 months; unwillingness to undergo regular pregnancy testing.
3. Hepatitis B & C or HIV infection
4. Anaemia ($Hb \leq 115g/l$), thrombocytopenia ($\leq 75 \times 10^9/L$) or neutropenia ($\leq 1.0 \times 10^9/L$), abnormal ferritin, vitamin D ($< 50nmol/L$), abnormal renal (creatinine $\geq 130umol/L$) or liver function ($ALT \geq 50 U/L$).
5. Obesity ($BMI \geq 30Kg/m^2$)
6. Co-existing autoimmune conditions excluding vitiligo, or positive for serum auto-antibodies suggestive of covert non-thyroidal autoimmunity
7. Any significant physical health condition that may explain persistent symptoms including cardiorespiratory disease, renal or hepatic failure, pancreatic disease, cancer (excluding non-melanoma skin cancer), nutritional deficiency, untreated chronic infection including TB
8. Previous hospitalisation due to psychosis, depression or anxiety, current HADS depression score > 10
9. Consumes more than 20 units of alcohol per week
10. Current use of medication that would interfere with mycophenolate action, including proton pump inhibitors.
11. Current use of medication that precludes thyroid FNA including warfarin and DOACs
12. Current use of immunosuppressive therapy for other conditions (within 3 months)
13. Current or previous participation in a CTIMP or interventional research study within 3 months
14. Hypersensitivity or anaphylactic reaction to mycophenolate mofetil or mycophenolic acid
15. Inability, in the opinion of the investigator, to be able to complete the clinical trial visits or procedures

Date of first enrolment

30/03/2025

Date of final enrolment

30/11/2026

Locations

Countries of recruitment

United Kingdom

Study participating centre

Royal Victoria Infirmary

Clinical Research Facility

Queen Victoria Road

Newcastle upon Tyne

United Kingdom

NE1 4LP

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Triumph@newcastle.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes