ISRCTN68248063 https://doi.org/10.1186/ISRCTN68248063

Trial of mycophenolate for persistent symptoms of hypothyroidism

Submission date
16/05/2025

Recruitment status
Recruiting

Registration date
17/07/2025

Overall study status
Ongoing

Last Edited
11/08/2025

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

Contact name
Dr Simon Pearce

Contact details
Translational and Clinical Research Institute, Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 191 2418674
simon.pearce@newcastle.ac.uk

Type(s)
Public

Contact name
Dr . Study Team

Contact details
Newcastle Clinical Trials Unit, Newcastle University, Baddiley Clark Building
Newcastle-upon-Tyne
United Kingdom
NE2 4NQ
+44 191 208 0656
triumph@newcastle.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1010665

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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)
Not yet submitted, To be confirmed, ref: 25/EM/0124

Study design
Interventional double blind randomized parallel group placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet

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

Pharmaceutical study type(s)
Pharmacodynamic, Therapy

Phase
Phase II

Drug/device/biological/vaccine name(s)
Mycophenolate mofetil Tillomed 500 mg film-coated tablets

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

Secondary outcome measures
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.

Overall study start date
12/05/2025

Completion date

30/04/2028

Eligibility

Key inclusion criteria
1. Female patients ≥18yrs and ≤50yrs 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

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
48

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 ≤ 115g/l), thrombocytopenia (≤75 x10^9/L) or neutropenia (≤1.0 x10^9/L), abnormal ferritin, vitamin D (<50nmol/L), abnormal renal (creatinine ≥130umol/L) or liver function (ALT ≥50 U/L).
5. Obesity (BMI ≥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 intervetional 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

Sponsor details
Joint Research Office, Regent Point, Regent Farm Road
Newcastle upon Tyne
England
United Kingdom
NE3 3HD
-
tnu-tr.sponsormanagement@nhs.net

Sponsor type

Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

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

Publication and dissemination plan
Peer reviewed scientific journals
Internal report
Conference presentation
Publication on website
Other publication
Participants will give consent for the sharing of their anonymised trial data with other researchers, published in medical journals and at research meetings.

Intention to publish date
30/04/2029

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