GOut TrEatment STrategy (GO TEST) FINALE study continuation versus cessation of urate lowering therapies in gout in remission.

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We hypothesize that the T2T strategy is superior compared to the T2S in retaining gout remission and is also more cost-effective.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON20243

Source
NTR

Brief title
GO TEST FINALE

Condition

- Joint disorders

Synonym
Inflammatory rheumatic disease, gout

Health condition

Gout, arthritis urica

Sponsors and support

Primary sponsor: Sint Maartenskliniek, Nijmegen
Source(s) of monetary or material Support: ZonMw/ZE&GG extra ronde 2019

Intervention

Explanation

Outcome measures

Primary outcome

The primary outcome is the difference in proportion of patients fulfilling an adapted version of the preliminary remission criteria for gout (no tophi, no flares, NRS pain due to gout < 2, NRS gout disease activity <2) over the last six months of 24 months follow up between the T2T and T2S strategy group. The adaptation consist of omitting the SU target < 0.36 prerequisite, as this surrogate outcome measure is of course not a realistic goal when comparing T2T and T2S.

Secondary outcome

- Non-inferiority of T2S compared to T2T with a predefined NI-margin of 0.08, in case superiority of T2T over T2S is not shown in the primary analysis. - The incremental cost-effectiveness of T2T over T2S treatment strategy in euro per QALY gained, by using the results of EQ-5D-5L, iMCQ, iPCQ and medication costs - The between group difference in the incidence (cumulative incidence and incidence density rate) of gout flares during the follow-up period of 24 months - The proportion of participants that require reintroduction of ULT in the T2S group during the 24 month follow-up period - The between group difference in SU change during the total follow-up time and particularly at baseline and at the end of follow-up at 24 months - The between group difference in PROMs at baseline and after 24 months by using the EQ-5D-5L, HAQ-II, NRS pain, and NRS global health - The between group difference in types and frequency of adverse events, with special focus on change in renal function (CKD-EPI), incidence of cardiovascular events during the follow-up period of 24 months - The between group difference in use of ULT and flare medication (colchicine, NSAIDs and/or glucocorticoids) - The (between group) difference in prescribed medication compared with refill rates during the follow-up period of 24 months - An overview of predictors for successful ULT cessation in the in the T2S strategy group including clinical, radiological, immunological and genetic variables

Study description

Background summary

Urate lowering therapies (ULT) are used in patients with gout to lower serum urate (SU) levels to prevent crystal depositions which can result in inflammation. Rheumatology guidelines recommend the use of ULT by the so-called treat-to-target strategy (T2T); SU levels should be <0.36 mmol/l or <0.30 mmol/l in severe gout, by increasing or combining ULT until the target has been reached. Due to the chronicity of gout, the high safety and low costs of ULT, most experts therefore advise to use ULT lifelong. However, a different, frequently used method (mainly by patients themselves or general practitioners, GPs) is a treat-to-symptom strategy (T2S), which only aims at a patient acceptable symptom state, regardless of SU levels. ULT are often stopped when in remission and are restarted when gout flares reoccur (too often). Although most rheumatologists strongly belief that the T2T approach is superior to T2S, high quality evidence to support either of the strategies is lacking, both in the induction phase but especially in the maintenance phase. We hypothesize that the T2T strategy is superior compared to the T2S in retaining gout remission and is also more cost-effective.

Study objective

We hypothesize that the T2T strategy is superior compared to the T2S in retaining gout remission and is also more cost-effective.

Study design

Visits: baseline, 2 weeks after ULT cessation, month 12, month 24 Questionnaires: flare monitoring monthly, other PROMs and medical costs three monthly

Intervention

Continuation or tapering to stop of urate lowering therapy

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- Patients with clinical diagnosis of gout and/or fulfilling the 2015 ACR-EULAR gout criteria - Use of ULT (allopurinol, benzbromarone and/or febuxostat) - Achieved remission for ≥ 12 months based on adapted preliminary gout remission criteria (29). o Free of flares and/or clinically apparent tophi during the last 12 months o Serum urate ≤0.36 mmol/l at baseline and all values in the last 12 months should not be >0.36 mmol/l o Pain due to gout <2 using a 10-point Likert-type scale at baseline o Patient global assessment of gout disease activity <2 using a 10-point Likert-type scale at baseline - Age ≥18 years and mentally competent - Signed written informed consent

Exclusion criteria

- Not being able to speak, read or write Dutch well enough - No ability to measure the outcome of the study in the participant (e.g. life expectancy <2 years, planned relocation out of reach of study center) - A strong contra-indication for glucocorticoids, NSAIDs AND colchicine, as this hampers flare treatment - Use of ULT (also) for any other indication than gout (for example nephrolithiasis) - Currently taking regular glucocorticoids, and/or colchicine, and/or interleukin-1 inhibitors for any diagnosis and/or the use of regular NSAID intake for gout activity - A history of myocardial infarction or stroke in the past six months and/or congestive heart failure NYHA class III or IV

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2021
Enrollment:	310
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	26-01-2021
Application type:	First submission
Review commission:	METC Oost-Nederland p/a Radboudumc, huispost 628, Postbus 9101 6500 HB Nijmegen 024 361 3154 commissiemensgebondenonderzoek@radboudumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 52436
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9245
CCMO	NL74350.091.20
EudraCT	2020-005730-15
OMON	NL-OMON52436

Study results