The Gout TrEatment STrategy Project (GO TEST) Overture trial

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The GO TEST OVERTURE study aims to demonstrate the superiority of the Treat to Target management strategy over a Treat to Avoid Symptoms approach in terms of clinical remission of gout symptoms.

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

Summary

ID

NL-OMON55282

Source
ToetsingOnline

Brief title
GO TEST OVERTURE

Condition

- Joint disorders

Synonym
Gout; Gouty arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Viecuri Medisch Centrum voor Noord-Limburg
Source(s) of monetary or material Support: ZonMw programma: Evaluatieonderzoek Zorg Evaluatie & Gepast Gebruik (ZE&GG) & ReumaNederland

Intervention

Keyword: Gout, Treat-to-Avoid-Symptoms, Treat-to-Target, Urate lowering therapy

Outcome measures

Primary outcome

The primary endpoint is superiority of T2T vs T2S in terms of 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 disease activity <2 over the last six months of 24 months follow up

Secondary outcome

Incremental net monetary benefit of T2T over T2S at cost-effectiveness ceilings ranging from ¤0 to ¤120.000 per Quality Adjusted Life year (QALY)

Proportion of patients achieving serum urate level at, or below, 0.3 mmol/l at 12 and 24 months

Proportion of patients achieving serum urate level at, or below, 0.36 mmol/l at 12 and 24 months

Proportion of patients developing clinically apparent tophi

Number of gout flares according to the Gaffo criteria from baseline to last follow up

Patient reported functional status by The Rapid-3 version of the Health

Assessment Questionnaire-II from baseline over 24 months (3-monthly)

Pain by Numerical Rating Scale from baseline over 24 months (3-monthly)

Patient Global assessment of Disease Activity by Numerical rating scale from

baseline over 24 months (3-monthly)

Study description

Background summary

Urate Lowering Therapy (ULT) plays an important role in the management of gout, however it can be implemented through different strategies. In the absence of high-quality evidence, international guidelines disagree which management strategy is optimal. The GO TEST OVERTURE study aims to assess the relative effect and cost effectiveness of two frequently used treatment strategies regarding ULT. These two strategies are the Treat to Target strategy, aiming at a serum uric acid of at least below 0.36 mmol/l and no complaints of gout/patient acceptable symptom state, and the Treat tot Target strategy, aiming only at the latter.

Study objective

The GO TEST OVERTURE study aims to demonstrate the superiority of the Treat to Target management strategy over a Treat to Avoid Symptoms approach in terms of clinical remission of gout symptoms.

Study design

randomized, multicenter, pragmatic, superiority trial

Intervention

Treat to Target

Patients in this group will be treated in accordance with the guidelines issued by the Dutch association for rheumatology (NVR) and the *European League against rheumatism* (EULAR). All patients initiate ULT at the start of the study, with an initial low dose that is then titrated upward until the SUA

target of <36 µmol / l , or <30 µmol / l is reached. During the first 6 months of the study, patients should be provided with prophylactic treatment against flares and SUA levels should be monitored regularly, in accordance with local procedures, until target SUA levels have been obtained. In the subsequent 18 months of the study, SUA levels will be measured at the 12 and 24 month study visits, and medication should be adjusted if the treatment target is not/no longer met. During the study period, rheumatoligsts may decide to schedule additional routine care visits for monitoring of SUA levels if this is deemed necessary.

Treat to avoid symptoms

Patients in this group will be treated in accordance with guidelines issued by the American college for Physicians. The treating rheumatologist and patient discuss the benefits and harms of initiating ULT including the option to not start ULT, start only low (safe) dose ULT, or simultaneously initiate anti-inflammatory prophylaxis, given the personal preferences and situation of the patient. When patient and rheumatologist decide to refrain from initiating ULT, recurrent flares can be treated if they occur with anti-inflammatory medication (NSAIDS, colchicine, glucocorticoids) without starting ULT. SUA levels will not be monitored, and no routine care visits are planned (12 and 24 months study visits are planned though), but patients will be instructed to report gout flares in the study E-CRF. Patients who report > 1 gout flare in the study CRF will be prompted to schedule a clinic visit. During these clinic visits patients and clinicians will revisit their decision regarding ULT.

Study burden and risks

Patient risk

This study is primarily aimed at comparing different forms of follow-up to uric acid lowering therapy. Various uric acid-lowering drugs and lifestyle advice play an important role in this. During the study, rheumatologists are free to prescribe uric acid-lowering drugs in consultation with the patients, with the aim to get the serum urate level to or below the target value in the Treat to Target group and with the aim to prevent recurrent symptoms in the Treat to Avoid symptoms. However, all drugs prescribed used in this study should be approved for use in gout in European countries and are
to be used in accordance with the EULAR recommendations for the treatment of patients with gout, as well as the updated management guidelines for 2020 issued by American College for Rheumatology. Therefore, patients are not exposed to additional treatment-related risks compared to routine clinical care due to their participation in this study.

Patient burden

The study will not interfere with care provided for patients. Patients will

visit the rheumatology clinic once per year. Clinical measures performed for this study are already part of routine care in The Netherlands. In addition to the burden imposed on patients by routine clinical care, patients will have to fill in questionnaires every three months, which might take approximately 20 minutes, each time

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Patients with a Clinical diagnosis of gout and/or fulfilling the 2015 ACR-EULAR criteria
• Hyperuricemia
• No current use of ULT

Exclusion criteria

• A strong Contraindication for all allopurinol, benzbromarone AND febuxostat ULT
• Kidney failuree defined as GFR < 30ml/minute
• Insufficient mastery of Dutch language to fill out questionnaires

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-03-2021
Enrollment:	310
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	adenuric
Generic name:	Febuxostat
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Desuric
Generic name:	Benzbromaron
Registration:	Yes - NL intended use

Product type:	Medicine
Brand name:	Zyloric
Generic name:	ALLOPURINOL
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-01-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-02-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-07-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-09-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-02-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	30-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26393
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2020-005721-82-NL
CCMO	NL74873.091.20
OMON	NL-OMON26393