The Gout TrEatment STrategy Project (GO TEST) Overture trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26393

Source
Nationaal Trial Register

Brief title
GO- TEST Overture

Health condition

Gout

Sponsors and support

Primary sponsor: VieCuri Medical Center
Source(s) of monetary or material Support: ZonMW & Reuma Nederland

Intervention

Outcome measures

Primary outcome

The GO TEST OVERTURE study aims to demonstrate the superiority of the T2T management strategy
over a T2S approach in terms of clinical remission of gout symptoms.

Secondary outcome

• In case superiority of T2T cannot be established, non-inferiority of T2S vs T2T will be tested
• To assess the cost effectiveness of a T2T gout management strategy compared with T2S
• To assess the effect of both treatment strategies on secondary clinical endpoints
• To assess the effect of both treatment strategies on patient reported outcomes
• To assess the safety of both treatment strategies

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 Gout TrEatment STrategy project (GO TEST) aims to compare clinical outcomes and cost-effectiveness of the Treat to Target (T2T) versus the Treat to avoid Symptoms (T2S) management strategies at two different points of the gout patients 'journey. The research protocol describes the GO TEST OVERTURE study in which gout patients not currently receiving ULT will be randomized to T2T or T2S and followed up for two years.

Study objective

The T2T strategy is superior in obtaining gout remission compared to the T2S strategy, and cost-effective.

Study design

Baseline, T1 (1 year follow-up visit), T2 (2 year follow-up visit)

Intervention

T2T strategy, starting ULT with the goal of obtaining clinical remission and a SUA target <0.36mmol/ or <0.30 mmol/l, intensifying ULT until targets are reached.

Contacts

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Eligibility criteria

Inclusion criteria

To be eligible to participate in this study, a subject must meet all the following criteria:
• Patients with a clinical diagnosis of gout and/or fulfilling the 2015 ACR-EULAR criteria
• Indication for ULT
• No current use of ULT

Exclusion criteria

A potential participant will be excluded from the study if one or more of the following criteria have been
met:
• A strong Contraindication for allopurinol, benzbromarone AND febuxostat
• eGFR < 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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	04-03-2021
Enrollment:	310
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
TBD

Ethics review

Positive opinion Date:	29-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55282
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9575
CCMO	NL74873.091.20
OMON	NL-OMON55282

Study results

Summary results
TBD