A diet for the treatment of gout

No registrations found.

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

Summary

ID

NL-OMON21749

Source
NTR

Brief title
DIEGO

Health condition

Gout

Sponsors and support

Primary sponsor: Reade
Source(s) of monetary or material Support: own funding

Intervention

Outcome measures

Primary outcome

Serum uric acid

Secondary outcome

cardiovascular risk, adherence, metabolic parameters, physical, mental and social health and costs

Study description

Background summary

Rationale: An unhealthy diet is an important modifiable risk factor for hyperuricemia and gout. Unhealthy diet is also associated with obesity and metabolic syndrome (MetS), known risk factors for gout as well as for cardiovascular disease (CVD). The prevalence of CVD is considerably elevated in patients with gout. Current treatment of gout mainly consists of medication and advice to lower alcohol consumption and avoid foods high in purine. Non-pharmacological therapies for gout, such as dietary interventions, have not yet been extensively studied. However, available evidence suggests that a Mediterranean-style diet could be the most suitable long-term dietary strategy for gout patients. A Mediterranean-style whole food plant-based diet (WFPD), that has been shown to be effective for the treatment of other metabolic syndrome- and obesity-related diseases (CVD and diabetes type 2), has not yet been studied in patients with gout.
Objective: To investigate the effect of a dietary intervention based on a WFPD on serum uric acid levels, gout disease activity and cardiovascular risk in patients with gout.
Study design: A 4-month randomized controlled trial (RCT), comparing a dietary intervention with usual care in patients with gout (n=30). The control group will receive the intervention after 4 months. After completion of the dietary intervention, all patients will be followed in a one-year extension study.
Study population: Patients diagnosed with gout according to the ACR 2015 criteria with hyperuricemia (♂ ≥ 7 mg/dL (0.42 mmol/L) and ♀ ≥ 6 mg/dL (0.36 mmol/L)) and not receiving urate lowering therapy.
Intervention: Personal counselling on a WFPD, based on the 3 hours of dietetic counselling eligible for reimbursement by the Dutch National Health Insurance. Counselling is divided into an introduction session of 60 minutes and four sessions of 30 minutes after 2, 4, 8 and 12 weeks. The control group receives usual care. During the one-year extension program subjects have 2 additional counselling sessions of 30 minutes.
Main study parameters/endpoints: The primary outcome for the RCT study is the difference in mean change in serum uric acid levels between intervention- and control groups. The primary outcome for the extension study is the mean within-subject change in serum uric acid levels from 0-16 months.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation includes 5 individual counselling sessions with a registered dietitian in the RCT phase, followed by two additional individual counselling sessions in the 12-months extension period. Subjects will undergo 3 measurement visits in the course of the RCT (or 5 if starting in the control group) and 2 measurement visits during the 12-month extension period. Blood sampling will stay below 80 ml per measurement and includes stored serum. Measurements include: questionnaires, physical exam and blood samples at all measurement visits and ultrasound at three measurement visits (T0, T2 and T4).
Given the nature of the intervention, there is no risk associated with participation, since the trial concerns healthy behavior. Subjects are motivated patients and they may see the intervention as an opportunity rather than a burden. Nonetheless, the intervention may be experienced as difficult or tough. All patients will receive the intervention, either directly or

after a waiting list period.
Patients with an indication for urate-lowering therapy (ULT) at baseline will not be included in this study unless shared decision making between patient and rheumatologist leads to the decision to postpone the start of ULT until after the RCT (if still necessary). This could give a delay of 4 months with possibly avoidable gout attacks and joint damage, although the period of delay is short.

Study objective

A 4-month WFPD
H0: has no effect on the levels of serum uric acid in patients with gout, hyperuricemia and abdominal obesity in comparison with usual care.
H1: results in decreased levels of serum uric acid in patients with gout, hyperuricemia and abdominal obesity in comparison with usual care. Based on our systematic review we expect a 1-3 mg/dl (0.06–0.18 mmol/L) decrease of serum uric acid.

Study design

Measurements at 0, 2, 4, 10 and 16 months

Intervention

The dietary intervention is a whole food plant based diet and it will be offered as an individual counselling package of in total 3 hours divided between introduction session (60 minutes) and four consecutive sessions of 30 minutes at 2, 4, 8 and 12 weeks. All counselling sessions will take place at Reade. The follow-up sessions can also take place online via video-call if physical face-to-face contact will not be possible due to the external circumstances (e.g. COVID-19 precaution measures).

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Diagnosis of gout confirmed by a rheumatologist (first or recurrent episode) based on the ACR criteria.
• Hyperuricemia (♂ ≥ 7 mg/dL (0.42 mmol/L) and ♀ ≥ 6 mg/dL (0.36 mmol/L)) (2).
• Waist circumference of ♂ ≥ 102 cm and ♀ ≥ 88 cm.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• Concurrent presence of other forms of inflammatory joint disease than gout.
• Intractable gout due to side effects or contra-indications for standard flare treatment (NSAIDs, colchicine and corticosteroids).
• Current use of urate lowering therapy or use of urate lowering therapy in the last 30 days.
• Indication for urate lowering therapy according national guidelines (NVR guideline gout 2013: https://www.nvr.nl/richtlijnen/nvr-richtlijnen-standpunten-en-zorgpaden/) including □2 flares in one year, tophaceous gout or history of urate urolithiasis. Unless agreement between patient and treating rheumatologist led to the decision to postpone the start of ULT for the duration of at least the first 4 months of the study.
• Pregnancy.
• Insufficient comprehension of Dutch language.
• Already following a (near-)vegan diet.
• In case of smoking, unwillingness to stop smoking for at least the duration of the study.
• Low e-health competencies (lowest proficiency according to Pharos quick scan, see appendix B).
• Inability to be scheduled for counselling and measurement visits.
• Psychiatric disease.
• No informed consent.

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2020
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	15-09-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8903

Register	ID
Other	METC VUMC : 2020.405 - NL74142.029.20

Study results