A pilot randomized controlled trial with a one-year extension period on the effect of a whole food plant-based diet for patients with gout

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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.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49186

Source
ToetsingOnline

Brief title
DIEGO

Condition

- Other condition

Synonym
gout

Health condition

gewrichtsaandoeningen: jicht en metabool syndroom/hart- en vaatziekten

Research involving
Human

Sponsors and support

Primary sponsor: Reade
Source(s) of monetary or material Support: Eigen financiering (Reade).

Intervention

Keyword: diet, gout, plant-based, uric acid

Outcome measures

Primary outcome

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 within-subject mean change in serum uric acid levels from 0-16 months.

Secondary outcome

Gout disease activity:

- Number of gout flares during the study. The definition of a gout flare is according to the patient (3 out of 4 criteria must be present): patient-defined gout flare, pain at rest>3 on a 0-10 point numerical rating scale, at least 1 swollen joint, at least 1 warm joint (Gaffo et al., 2018).
- Mean duration of gout flares in days
- Flare intensity measured with Visual Analogue Scale for pain (VAS 0-10)
- Gout specific functioning and health will be measured using the validated Dutch Gout Assessment Questionnaire (GAQ2.0) (Spaetgens et al., 2014).
- Use of gout flare medication including pain relief medication, NSAID*s, COXIBs, colchicine and corticosteroids (duration, dose, area under the curve (AUC)).

Cardiovascular risk score and risk factors:

- 10-years risk for fatal CVD (composite endpoint of age, gender, systolic

blood pressure, cholesterol ratio and smoking status) (Conroy et al., 2003).

- Arterial stiffness (as measured with the surrogate markers IMT and PWV).

- Blood pressure

- Body mass index

- Waist circumference

- Lipid profile: total cholesterol, LDL, HDL, triglycerides

- Fasting plasma glucose

- Hb1ac

WFPD diet adherence:

- adherence to a WFPD from 0-12 months

Study description

Background summary

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.

Study 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.

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.

Study burden and risks

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 (T0, T2 and T4) measurement visits.
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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnosis of gout confirmed by a rheumatologist (first or recurrent episode) based on the ACR criteria (Neogi et al, 2015).
Hyperuricemia (* * 7 mg/dL (0.42 mmol/L) and * * 6 mg/dL (0.36 mmol/L)) (Duskin-Bitan et al., 2014).
Waist circumference of * * 102 cm and * * 88 cm.

Exclusion criteria

- 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 gout 2013) including 2 or more 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)
- Inability to be scheduled for counselling and measurement visits.
- Psychiatric disease.
- No informed consent.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2020
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-08-2020

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-12-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL74142.029.20