Gout in general practice

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Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21536

Bron
NTR

Verkorte titel
GRIP

Aandoening

Gout, gouty arthritis, jicht

Ondersteuning

Primaire sponsor: Erasmus MC, department of General Practice
Overige ondersteuning: ZonMW (Dossier number 80-83910-98-13051)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Frequency of patients’ reported gout attacks and the presence of tophi.

Toelichting onderzoek

Achtergrond van het onderzoek

Objectives:

1. What is the frequency of self-reported gout attacks of patients diagnosed with gout in general practice?

2. What is the prevalence of tophi in patients diagnosed with gout in general practice?

3. Does the use of allopurinol decrease the self-reported gout attack frequency in patients diagnosed with gout in general practice?

4. Does the use of allopurinol decrease the presence of tophi in patients diagnosed with gout in general practice?

5. Are patient characteristics and lifestyle factors (BMI, smoking status, physical activity, social status) associated with the frequency of gout attacks in patients diagnosed with gout in general practice?

6. Is the consumption of fructose rich beverages, carbonated beverages, alcohol, purine rich food, lactose and dairy products associated with the frequency of gout attacks in patients diagnosed with gout in general practice?

7. Is the use of medication, such as diuretics and salicylates, associated with the frequency of gout attacks in patients diagnosed with gout in general practice?

Study design: Prospective observational cohort study, at baseline patients will fill in questionnaires, and a physical examination (blood pressure measurement, BMI) and a blood sample will take place. During the two year follow-up, 8 questionnaires will be filled in (1 every 3 months) by the patients.

Study population: Adult patients who contacted their GP due to a gout attack in the year 2013, 2014 or 2015 will be invited to participate. We aim to include 1300 patients.

Main study parameters/endpoints: We will assess:

- Primary outcomes: Frequency of patient reported gout attacks and the presence of tophi.

- Secondary outcomes: body-mass index, smoking status, fructose-rich/carbonated beverages and alcohol consumption, purine rich food intake, lactose and dairy intake, education level, compliance to prescribed medication for gout, use of (over the counter) medication, physical activity, co-morbidity, and quality of life.

- Physical examination: blood pressure, BMI.

- Laboratory serum examination: estimated glomerular filtration rate, uric acid level, cholesterol, low and high-density-lipoproteïne cholesterol, and glucose (fasting).

Doel van het onderzoek

In the Netherlands, 90% of the patients with gout are managed by general practitioners but most research has been done in secondary care. In primary care there are questions on the clinical relevance of long-term uric acid lowering treatment of gout on e.g. the recurrence and frequency of gout arthritis. It is also unclear whether factors such as diet, overweight and use of medication might be associated with gout attack frequency.

Onderzoeksopzet

• Frequency and characteristics of gout attacks (modified GAQ 2.0) – every 3 months. Presence and burden of tophi (TIQ-20) – baseline, 1 year, 2 years.

• Demographics – baseline.

• Laboratory serum examination, blood pressure and BMI (physical examination) – baseline.

• Comorbidity (SCQ) – baseline, 1 and 2 years follow-up. Physical and mental health (SF-36); quality of life (EQ-5D) – baseline, 1 and 2 years.

• The use and adherence to allopurinol and other gout-medication – every 3 months. The adherence to other prescribed medication and over the counter medication (derived version of the BMQ) – baseline, 1 year, 2 years.

• Diet (Dutch validated FFQ) – baseline, 1 year, 2 years.

• Physical activity (IPAQ) and smoking status – baseline, 1 and 2 years follow-up.

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

Publiek

Postbus 2040

K.D.B. Van Leeuwen
Rotterdam 3000 CA

The Netherlands
003110-7044750

Wetenschappelijk

Postbus 2040

K.D.B. Van Leeuwen
Rotterdam 3000 CA
The Netherlands
003110-7044750

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age: older than 18 years.

Contacted his/her general practitioner with a gout attack in the year 2013, 2014 or 2015. The presence of gout will be validated at baseline according to the 2015 ACR-EULAR criteria for gout and the Diagnostic rule (Gout calculator).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with a limited life expectancy.

Patients that are not able (independently or with help) to fill in the Dutch questionnaires.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-02-2017
Aantal proefpersonen:	681
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5963
NTR-old	NTR6329
Ander register	ZonMW Protocol ID; CCMO; MEC : 80-83910-98-13051; NL.57154.078.16; MEC-2016-437

Resultaten