Gout: risk factors and treatment in primary care

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Primary Research Questions: 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...

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

Summary

ID

NL-OMON47414

Source
ToetsingOnline

Brief title
GRIP study

Condition

- Joint disorders

Synonym
gout, Gouty arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Huisartsgeneeskunde
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Gout, Primary care, Risk factors, Treatment

Outcome measures

Primary outcome

The main study endpoints are the frequency of gout attacks, the presence of tophi and the use of Allopurinol. The presence of gout will be validated according to the ACR-EULAR 2015 criteria for gout and the gout calculator. The frequency and characteristics of gout attacks will be measured using the modified Gout Assessment Questionnaire 2.0. The presence and burden of tophi will be measured using the validated Tophus Impact Questionnaire (TIQ-20). The use of allopurinol will be ascertained using the Brief Medication Questionnaire.

Secondary outcome

1. Demographics measured at baseline using questions derived from the Medical Consumption Questionnaire.

2. Tests include the following laboratory examinations: estimated glomerular filtration rate (eGFR), uric acid level, total cholesterol, low- and high-density-lipoproteïne cholesterol and glucose (fasting). Therefore, at baseline a single venapunction will take place at baseline. Blood pressure will be measured once at baseline.

3. Clinical factors: Comorbidity will be assessed at baseline, 1 year and 2 years FU using the Self-Administered Comorbidity Questionnaire. For calculating BMI, at baseline the patients length and weight will be asked. Physical and mental health will be determined at baseline, 1 year and 2 years using the

SF-36 physical and mental component summary [18] and quality of life via the EQ-5D.

4. Medication: The use and adherence to allopurinol and other gout-medication will be evaluated every 3 months. The adherence to prescribed medication and over the counter medication will be measured at baseline, 1 year and 2 years follow-up using a derived version of the Brief Medication Questionnaire.

5. Diet and lifestyle: Dietary intake (consumption of fructose-rich and carbonated beverages, alcohol, purine rich food, lactose and dairy products) will be measured using the Dutch validated Food Frequency Questionnaire, at baseline, 1 and 2 years follow-up. Physical activity will be measured at baseline and hereafter every 6 months with the International physical activity questionnaire. Smoking status will be asked at baseline, 1 year and 2 years follow-up.

Study description

Background summary

In the Netherlands, 90% of the patients with gout are managed by GPs 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. It is also unclear whether factors such as diet, overweight and use of medication might be associated with gout attack frequency.

Study objective

Primary Research Questions:

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?

Secondary Research Questions:

5. Are patient characteristics and lifestyle factors (presence of cardiovascular risk 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

Study burden and risks

The burden will be minimal for patients participating in this study. Patients will visit their GP once for blood pressure measurement, measurement of weight and length and for collecting the blood sample. The patient fills out 12 questionnaires which takes some time (30 min); Physical and psychological discomfort will be minimal, since the questionnaires will mostly assess diet, medication use and physical comorbidities.

Contacts

Public
Selecteer

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NL
Scientific
Selecteer

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age: older than 18 years.
- Contacted their GP with a gout attack in the year 2013, 2014 or 2015

Exclusion criteria

- Patients with a limited life expectancy.
- Patients that are not able (independently or with help) to fill in the Dutch questionnaires.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-02-2017
Enrollment:	681
Type:	Actual

Ethics review

Approved WMO Date:	03-11-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-12-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-02-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-02-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL57154.078.16