Real-time monitoring the occurrence of gout flares in patients by incorporation of the 2017 gout flare definition into an eHealth platform. A feasibility study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21867

Source
Nationaal Trial Register

Brief title
Jicht app studie

Health condition

gout / jicht
self-diagnosis / zelf-diagnose
eHealth

Sponsors and support

Primary sponsor: Sint Maartenskliniek Nijmegen
Source(s) of monetary or material Support: AbbVie

Intervention

Outcome measures

Primary outcome

What is the perceived patients' value of thirty patients of app-based platform Q1.6 for identification of gout flares as operationalized by the perceived usefulness and ease of use?

Secondary outcome

a) What is the perceived ease of use as rated by the system usability score of the Q1.6 gout app?

b) What is the perceived usefulness of the Q1.6 gout app?

c) How often are gout flares reported per patient per 3 months?

d) What proportion of flares lasts longer than three days?

Study description

Background summary

Rationale: In current practice gout flares are recorded during outpatient clinic visits when flares have long past and thus are subject to recall bias. In the ideal situation gout flares are recorded while occurring. Recently, a four-criteria gout flare definition has been validated [Gaffo et al. Arthritis Rheumatol 2018]. This definition has primarily been developed and validated for use in clinical studies. In this study we want to test if it is feasible to apply the gout flare definition in the home situation using a mobile app.

Objective: Purpose of this descriptive study is to gauge the feasibility of the Q1.6 app as platform to measure gout flares in real time.

Study design: A descriptive cross-sectional study

Study population: Thirty adult patients with (a high clinical suspicion of) gout who have reported a gout flare in the last twelve months.

Intervention (if applicable): Use of mobile app Q1.6 which will ask 1 - 4 questions daily for three consecutive months concerning the presence of a possible gout flare.

Main study parameters/endpoints: The perceived patient's value of the Q1.6 gout app as measured by the system usability scale (=perceived ease of use) and perceived usefulness questionnaire.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects will be asked 1 – 4 questions daily through a mobile phone application for three consecutive months. At the end of the study several questionnaires have to be answered (digitally). There are no extra visits planned during this study. All other actions

taken are part of usual care and are according to local gout protocol. Participation in the study will not lead to additional medical care, medication or diagnostic procedures. The burden on subjects is minimal and non-invasive.

Study objective

We hypothesize that by combining the recently validated gout flare criteria with a patient-friendly app and real-time monitoring, we can implement a gout flare measure that is less prone to recall bias and can be used by patients at home. It could measure flares more accurate and create a possibility to act upon flares faster, thereby improving patient outcomes in a treat-to-target strategy.

Study design

T = 90 days

Intervention

Use of mobile app Q1.6 which will ask 1 - 4 questions daily for three consecutive months concerning the presence of a possible gout flare.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients aged ≥18 years

- A diagnosis of crystal proven gout or a high clinical suspicion of gout

- Possession of a smartphone (android or apple-based)

Exclusion criteria

- Stable gout with no flares over the last year

- Life expectancy less than 3 months

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2018
Enrollment:	30
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 23-04-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45981
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6435
NTR-old	NTR7226
CCMO	NL65917.091.18
OMON	NL-OMON45981

Study results