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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21867

Bron
NTR

Verkorte titel
Jicht app studie

Aandoening

gout / jicht
self-diagnosis / zelf-diagnose
eHealth

Ondersteuning

Primaire sponsor: Sint Maartenskliniek Nijmegen
Overige ondersteuning: AbbVie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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?

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

T = 90 days

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Sint Maartenskliniek, Research department

Bart Pouls
Hengstdal 3

Ubbergen 6574 NA
The Netherlands
0031 24 327 2518

Wetenschappelijk

Sint Maartenskliniek, Research department

Bart Pouls
Hengstdal 3

Ubbergen 6574 NA
The Netherlands
0031 24 327 2518

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Stable gout with no flares over the last year

- Life expectancy less than 3 months

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2018
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-04-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45981
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten