Dynamic disease activity monitoring in Psoriatic Arthritis by novel personalized digital biomarkers*

Published: 04-05-2022
Last updated: 05-04-2024

To identify discriminatory features of smart phone and smart watch technology data to assess disease activity and if successful to evaluate the chosen technologies in a larger patient group with different levels of clinical disease activity in...

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52261

Source
ToetsingOnline

Brief title
PsAI

Condition

- Joint disorders

Synonym
arthritis psoriatica

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: farmaceuten,Pfizer

Intervention

Keyword: Arthrits Psoriatica, Development, Digital biomarker, Disease Activity

Outcome measures

Primary outcome

As described above we aim to develop digital biomarkers of disease activity which could include data from the accelerometers of the telephone, metadata of the keystroke path possibly combined with camera data. This will be then compared to clinical disease activity and self-reported symptoms.

Clinical disease activity is measured by validated measures of disease activity: Minimal disease Activity * MDA - [20], Psoriatic Arthritis Disease Activity Score (PASDAS)[22], and Disease Activity Psoriatic Arthritis) (DAPSA)

Secondary outcome

not applicable

Study description

Background summary

The level of disease activity in Psoriatic Arthritis determines the actions the rheumatologist takes to optimise treatment outcome among patients with this disease. Currently disease activity is measured by a combination of clinical measures and patients self-reported symptoms and functional ability. This requires the patients to visit the outpatient clinic on regular intervals., which during Covid-19 pandemic was not always possible. The use of questionnaires to collect Patients Reported Outcome (PRO*s) is a feasible option, the questionnaires fatigue is however a known limiting factor from a long term perspective. Currently there is no valid alternative for remote unobtrusive disease activity monitoring.

The wide spread use of smart devices by the general population, such as smartphone or smartwatch, provides opportunities to develop and study possibilities for Unobtrusive Remote Disease activity monitoring (URD) using

behavioural data captured by the sensors embedded within the smartphones/smartwatches. We hypothesize that high level of disease activity in Psoriatic Arthritis (PsA) will lead to lower degree of physical activity as registered by patients* smartphone as compared to a low disease activity state. Additionally, digital biomarkers are likely to provide information on other disease characteristics such as tiredness and sleep problems. Adding these will enhance discriminative ability of our approach. We also hypothesize that the information acquired by digital biomarkers will be comparable to the information received through usage of clinical measures and PROs. Last but not least, we hypothesize that patient will see the use of smartphone data as safe privacy-wise and a fair deal in return for lower amount of follow-up appointments at the out-patient clinic.

Overarching aim: To dynamically monitor the current status of disease activity in Psoriatic Arthritis (PsA) patients using novel personalized digital biomarkers to allow for early treatment adjustments, better disease control and lessen the burden of follow up visits.

Study objective

To identify discriminatory features of smart phone and smart watch technology data to assess disease activity and if successful to evaluate the chosen technologies in a larger patient group with different levels of clinical disease activity in Psoriatic Arthritis patients

Study design

An explorative longitudinal study will be set up using Design Thinking principals involving patients from set up onwards. The study consists of 2 stages. Stage 1 aims to find relevant data sources in smart devices and stage 2 aims to test the most promising features of stage 1 in a larger, but still modest, patient sample

Stage 1
Define
In the Define phase, the problem will be rephrased and a framework will be provided for functional and non-functional user requirements (mandatory, desired, optional) for possible solutions. This will be done by the research team consisting of patients (n=5), doctors (n=3), specialized rheumatology nurses(n=3) and researchers/technicians (n=8).

Digital disease activity measure - Prototype development
We plan to use technics build on the extensive experience and previous work by the AUTH* and FMH# in using artificial intelligence (AI)-based digital biomarkers in the monitoring of disease activity and progression in Parkinson*s Disease (www.i-prognosis.eu). By creating a behavioral feature vector, derived

from the advanced processing of each PsA patient*s interaction with her or his smart device, novel personalized digital biomarkers can be formed that capture subtle changes towards the evolution of the PsA symptoms over time. The related data sources in smart devices may include: a) 3-axes accelerometer/gyro (to measure body's specific force and movement; b) keystroke dynamics (virtual keyboard on smart devices) that may relate with upper extremity activity; c) smartphone camera, to acquire the nails, skin and eye status, for signs of inflammation as part of systemic involvement in PsA. It also might be part of the solution to use a smartwatch for acquiring data on heartrate/sleep changes. Another example may be intelligent gamified tests that includes gamified exercises to be followed by the PsA patient in a periodic manner. Patients* interaction within the game is captured by smartphone camera and provide data for digital marker to quantify patients* range of motion, balance and coordination status over time
The identified solutions will be graded according to pre-set requirements from the Define phase. In the Proof-of-concept phase, one or more working prototypes will be constructed and tested in 10 patients in several *test and adjust* cycles. This will provide us with a feasible solution to be tested among a larger sample of patients in stage 2

Stage 2
In the early exploratory test phase, the digital biomarker(s) will be tested in daily clinical practice over a 3-month period. To do so, we propose to ask 80 individuals to participate: 40 patients with low disease activity and 40 newly diagnosed patients with a high level of disease activity.
Clinical disease activity will be captured by the treating physicians as part of usual care at start and finish of the 3-month study interval. As patients are already participating in DEPAR (DEPAR MEC-2012-549) we aim to use DEPAR data for the purpose of this study. In brief, in the first year of DEPAR each patient is evaluated at 3-month intervals by both the treating physician and a research nurse and fills out the standard DEPAR PROs. In the second year this is at 6-month intervals followed by yearly intervals. As we aim to capture digital disease activity over a 3-month period we will schedule additional visits for those patients that have no clinical or study visit close by.
Digital disease activity will be captured by the method developed in stage 1, for which we currently assume it will be an app to be installed on the mobile phone. This will be accompanied by questions on pain, fatigue, skin irritation and stiffness (Likert Scale) that will be generate in a random sequence 1 to 3 times over a 24-hour period, taking a few seconds to be answered. The latter will provide us with information to assess the disease symptoms over time outside the window of the clinical assessment of disease activity.

Study burden and risks

There are no health risks associated with participation in this study

Burden

Patients will be requested to install an app on their phone that will collect the metadata of the keystrokes and the accelerometer data of the phone. In the app they have full control of the data they want to share. This means that they could stop data sharing at all times without asking our permission.
To monitor the levels of pain, fatigue and stiffness during the day the app will also send requests to complete questions on these symptoms. This will be very short questions that are answerable within a few seconds. These questions will appear between 1 to 3 times a day.
Clinical disease activity will be monitored each 3 months as described above. For most patients this will be a regular visit to the physician. If they only visit their physician at 6 months or at longer intervals, they are asked to have an additional 3 month appoint for clinical disease activity assessment
As participants already participate in DEPAR we will use their DEPAR self-reported measures. If they are diagnosed less than 12 month ago no additional work is required. If they participate longer than 12 months they may receive additional questions if we could not combine the current data collection with their regular DEPAR visit. This will take about 10 minutes extra per visit.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molenwaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molenwaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

active disease defined as not in MDA - 30 patients
inactive disease defined as in MDA - 30 patients
healthy controls - 20 subjects

Exclusion criteria

other disease that linfluence movement such CVA, prostethic limb etc in patients and sport trauma in healthy controls

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Not approved

Date:	04-05-2022

Application type:	First submission
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	NL78550.078.21