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Clinical study of medical devices for quantifying and/or classifying motor deficits in patients with Parkinson's disease or essential tremor - Clinical study for ANLIVA™ Dyskinesia & ANLIVA™ Eye Movement

Submission date
01/12/2023

Registration date
14/12/2023

Last Edited
28/10/2024

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to see if medical devices can be used for quantifying and/or classifying motor deficits in patients with Parkinson's disease and essential tremor.

Who can participate?
Patients diagnosed with Parkinson's disease or essential tremor and healthy control volunteer control subjects aged between 18 and 80 years old

What does the study involve?
The study involves measurements/data acquisition of motor deficits with a smartphone of ocular movements by using an advanced tracking camera device in combination with a computer.

What are the possible benefits and risks of participating?
The possible benefits include making an objective quantification and/or classification of tremor /hyperkinesia and an objective quantification of ocular movements.

The methods used in the study do not use any physical interventions, but the eye-tracking camera could be perceived as an intrusion of privacy.

Where is the study run from?
Uppsala University Hospital and Sahlgrenska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
August 2022 to October 2023

Who is funding the study?
1. VINNOVA Swedish Governmental Agency for Innovation Systems (Sweden)
2. Stardots AB (Sweden)

Who is the main contact?
Martin Nilsson (Stardots AB), martin.nilsson@stardots.se (Sweden)

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Public, Scientific

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Additional identifiers

Protocol serial number
DOC-303

Study information

Scientific Title
Patients with tremor or hyperkinesia or with ocular motor deficits such as e.g. patients with Parkinson's disease or essential tremor.
Measurement/ quantification of tremor or hyperkinesia using the mobile sensors of a Smartphone or of eye movements by using an advanced tracking camera device in combination with a computer
No comparator
Complications/adverse events and statistics of such; Correlation and accuracy of quantification of tremor or hyperkinesia or correlation and accuracy of the eye movements.

Study objectives
Is it possible to use medical devices ANLIVA™ Dyskinesia and/or ANLIVA™ Eye Movement to quantify and/or classify motor deficits in patients with Parkinson’s disease or essential tremor?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/02/2023, Gothenburg Department 1 Medicine (Box 2110, Uppsala, SE-75002, Sweden; +46(0)10-4750800; registrator@etikprovning.se), ref: CIV-ID 22-11-041486

Primary study design
Observational

Study design
Double-center open-label controlled exploratory pilot stage study

Study type(s)
Other, Safety

Health condition(s) or problem(s) studied
Parkinson's disease and essential tremor

Interventions
This exploratory pilot study aims to assess mathematical algorithms' performance using smartphone sensor data and eye tracking in individuals with Parkinson’s disease and essential tremor. The study involves using a medical device that will not impact participants physically.

Data collected from the device will be compared to assessments conducted by a qualified medical professional (Neurologist) to evaluate the accuracy and reliability of the algorithms in measuring and correlating relevant data.

The subjects participate in one visit, which takes less than one hour per visit. The sessions are held at healthcare institutions and neurological clinics at two university hospitals.

The participants are asked in advance if they are willing to participate with a description of what is needed, they then book a date for when to visit the clinic, visit the clinic and sign the informed consent. They are given the info from the Patient Information Sheet and will do the following tests: i) move a mobile phone from table to ear and back to table position 3 times with each hand; ii) sit down in front of a computer and look at moving dot on the computer screen and an advanced camera records the eye movements; and, iii) have an assessment of their status by health care personnel. No intervention is done, i.e. no change in any medication nor anything else that changes the medical state the subject is in. The test with a mobile phone takes less than a minute. The test when looking at a computer screen takes 2 minutes.

ANLIVA™ Dyskinesia measures movement disturbances from a “perfect” trajectory and uses sensors in the mobile phone (accelerometers, gyroscope etc) to get the deviation.

ANLIVA™ Eye Movement measures eye movements, more specifically how the pupil moves when the subject is looking at the moving dot on the screen. It is not easy to say exactly what is measured, but in one way it is the angle difference the camera is detecting or the distance the eye has rotated relative to the face.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ANLIVA™ Dyskinesia, ANLIVA™ Eye Movement

Primary outcome(s)
1. Movement disorder of hands measured using sensors in a mobile smartphone when the subject moves the mobile phone in a certain pattern, for approx. 1 minute during a visit to the clinic under supervision by healthcare personnel. This is for the ANLIVA™ Dyskinesia.
2. Movement disorder of eyes measured using an advanced camera when the subject looks at a computer screen and follows how a pattern moves on a computer screen, for approx. 2 minutes during a visit to the clinic under supervision by healthcare personnel. This is for the ANLIVA™ Eye Movement.

Key secondary outcome(s)
The following secondary outcome measures are measured using data recorded during the clinic visit:
1. Correlate the result of tremor and hyperkinesia detection with a neurologist assessment
2. Accuracy of classification between ET- and PD-induced tremor or hyperkinesia
3. Receiver Operating Characteristic (ROC) curve analysis
4. Accuracy of classification
5. Receiver Operating Characteristic (ROC) curve analysis

Completion date
01/10/2023

Eligibility

Key inclusion criteria
1. Patients already diagnosed with PD or ET or Healthy volunteers
2. Able to understand and sign the informed consent.

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
52

Key exclusion criteria
1. No signing of the informed consent
2. Below 18 years of age
3. Involvement in the planning and conduct of the clinical investigation (applies to all Stardots management staff, investigational staff and third-party vendors as applicable).

Date of first enrolment
15/03/2023

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
Sweden

Study participating centre

Uppsala University Hospital, Uppsala, Sweden
Akademiska sjukhuset, Uppsala
Uppsala
Sweden
75185

Study participating centre
Sahlgrenska University Hospital, Gothenburg, Sweden
Sahlgrenska Universitetssjukhuset, Göteborg.
Gothenburg
Sweden
41345

Sponsor information

Organisation
Stardots AB

Funder(s)

Funder type
Industry

Funder Name
Stardots AB

Funder Name
VINNOVA

Alternative Name(s)
Swedish Governmental Agency for Innovation Systems, Vinnovase

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Martin Nilsson (Stardots AB), martin.nilsson@stardots.se (Sweden). Data will be shared data with principal investigators. Investigators may share participant data with participants as the sponsor is unaware of who the participants are.

IPD sharing plan summary
Available on request