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Evaluation of autoSCORE: an artificial intelligence based algorithm for EEG classification versus human experts

Submission date
18/03/2022

Recruitment status
No longer recruiting

Registration date
25/03/2022

Overall study status
Completed

Last Edited
05/09/2023

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Electroencephalography (EEG) measures electric brain activity using electrodes attached to the scalp. This is used to investigate brain disease, most commonly epilepsy, coma, and dementia. The clinical interpretation of EEGs is until now mainly based on expert visual analysis, and there are indications that EEG reviewers are under increasing time pressure. A large, anonymized dataset consisting of EEGs evaluated and annotated by experts with a dedicated software package (SCORE EEG) is used to train an algorithm (autoSCORE) to automatically assess EEGs. autoSCORE is trained to separate normal from abnormal EEGs. When autoSCORE assesses the EEG as abnormal it will further sub-classify abnormalities into four sub-groups, which provide important information for medical decisions on patient management. This is a human expert validation study to validate the algorithm.

Who can participate?
This study involves analysis of recorded electroencephalography data. Direct participation of new patients is not required.

What does the study involve?
Doctors will assess 100 EEGs and the algorithm will assess the same EEGs. A large independent EEG dataset from Oslo University Hospital will be used to compare autoSCORE with the clinical scorings of the experts who evaluated the EEGs. The goal is to prove that the autoSCORE algorithm is non-inferior to human experts. The researchers will compare autoSCORE with a commercially available EEG analysis software package (ENCEVIS).

What are the possible benefits and risks of participating?
As the study involves analysis of the EEG data of patients who were referred to the investigation as part of their diagnostic work-up, there are no additional risks for the patients. EEG is a non-invasive procedure without any risks. The benefits are EEG diagnostics will become available also in underserved areas where EEG experts are not available, and it will assist physicians in reducing their workload in places where the expertise is available.

Where is the study run from?
1. Danish Epilepsy Centre Filadelfia (Denmark)
2. Haukeland University Hospital (Norway)
3. Oslo University Hospital (Norway)
4. Mayo Clinic (USA)

When is the study starting and how long is it expected to run for?
June 2020 to March 2022

Who is funding the study?
Holberg EEG (Norway)

Who is the main contact?
Prof. Sandor Beniczky
sbz@filadelfia.dk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Sandor Beniczky

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
24084-01

Study information

Scientific Title
Accuracy of EEG classification by autoSCORE algorithm compared with human experts

Acronym
autoSCORE

Study objectives
The autoSCORE algorithm has an accuracy similar to human experts in distinguishing abnormal from normal electroencephalography (EEG) recordings and classifying the abnormal recordings: focal-epileptiform, generalized-epileptiform, focal-slowing, diffuse-slowing.

AutoSCORE is an algorithm developed using artificial intelligence, based on a large SCORE dataset. The validation process is prospective, i.e. after the development of the algorithm, using a fixed algorithm and threshold (cut-off) value.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study uses anonymized EEG datasets and does not require ethics approval. The study has been reviewed on 07/07/2020 by the institutional review board and the data safety officer at the institution of the Principal Investigator, the Danish Epilepsy Centre, Filadelfia (Kolonivej 1, 4293, Dianalund, Denmark; +45 (0)58264200; pwo@filadelfia.dk), ref: Sagsnr. 0100256

Study design
Cross-sectional validation study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Patients suspected of epilepsy or other conditions with impaired consciousness or cognition

Interventions
EEGs will be automatically assessed by the previously developed autoSCORE algorithm using pre-defined detection thresholds. The algorithm first distinguishes between normal and abnormal recordings. Then, it classifies the abnormal EEGs into four categories: focal-epileptiform, generalized-epileptiform, focal-slowing, diffuse-slowing.

The performance of autoSCORE will be compared with the evaluation of the EEGs by a panel of experts on an independent dataset of a balanced sample of 100 randomly selected EEGs and form a large independent dataset from a hospital that did not participate in the development of the algorithm.

Intervention Type
Other

Primary outcome measure
Sensitivity, specificity, accuracy, positive predictive value, negative predictive value of autoSCORE compared with the majority-consensus scoring of the human experts, calculated using a balanced sample of 100 randomly selected EEGs at a single timepoint

Secondary outcome measures
Calculated using a balanced sample of 100 randomly selected EEGs at a single timepoint:
1. Inter-test agreement (autoSCORE vs human experts) in the large, independent dataset
2. Performance of autoSCORE at identifying recordings with epileptiform abnormalities (both focal and generalized) compared with the commercially available spike-detector software packages

Overall study start date
01/06/2020

Completion date
18/03/2022

Eligibility

Key inclusion criteria
The EEGs to be selected for this study have not been part of the training dataset to develop the autoSCORE. The datasets are distributed between the EEGs arriving from Haukeland University Hospital, Danish Epilepsy Centre Filadelfia and Mayo Clinic. Although there is no scientific reason to consider that ethnicities or geographical origin of the EEG, nor the software used for acquisition influences the results, in order to avoid any such potential bias, the study design has addressed this by using EEGs from different geographies. Age range: 35% under 16 years (pediatric population), 65% over 16 years (adult population).

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
100

Total final enrolment

100

Key exclusion criteria
1. Neonatal
2. EEGs reported with rhythmic and periodic patterns in critically ill patients

Date of first enrolment
01/06/2021

Date of final enrolment
18/03/2022

Locations

Countries of recruitment
Denmark

Norway

United States of America

Study participating centre
Danish Epilepsy Centre Filadelfia
Kolonivej 1
Dianalund
Denmark
4293

Study participating centre
Haukeland University Hospital
Haukelandsveien 22
Bergen
Norway
5009

Study participating centre
Mayo Clinic, Florida
4500 San Pablo Rd S
Jacksonville
United States of America
FL 32224

Sponsor information

Organisation
Holberg EEG AS

Sponsor details
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Sponsor type
Industry

Website
https://www.holbergeeg.com/

Funder(s)

Funder type
Industry

Funder Name
Holberg EEG AS

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
09/09/2023

Individual participant data (IPD) sharing plan
Additional information, including raw data, is available on request, pending IRB approval for the intended use. Please contact Prof. Sandor Beniczky (sbz@filadelfia.dk). Type of data: anonymised EEG, diagnostic gold standard; demographics (age, gender), output of the algorithm. Data will be available upon request for 10 years from the publication for scientific non-commercial use. As the dataset is de-identified, there is no need for consent from the participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4	28/02/2022	24/03/2022	No	No
Results article		01/08/2023	05/09/2023	Yes	No