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Use of artificial intelligence to identify visual problems in children

Submission date	Recruitment status	[_] Prospectively registered
21/05/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/05/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2023	Eye Diseases	

Plain English summary of protocol

Background and study aims
The World Health Organization (WHO) estimates that there are 19 million children in the world with visual impairment. Reports confirm that 70-80% of all visual impairments are either preventable or curable if detected in time. Most of these children will remain undiagnosed for years, leading to consequences on their vision, general development, educational opportunities, social life and prospects. All the tools currently available to assess visual function require active collaboration from the patients and/or an experienced examiner. An accurate and easy-to-use tool to identify children with abnormal visual development when they are as young as 6 months of age would be a major opportunity to prevent visual impairment in childhood. The aim of this study is to develop an accurate and easy-to-use tool to identify children with abnormal visual development.

Who can participate?
Any child aged between 6 months and 14 years, with no previous eye surgery other than laser or intravitreal treatment for retinopathy of prematurity.

What does the study involve?
All the participants undergo a complete eye assessment and a test of visual functions with a new digital test, presented on a screen, assisted with eye-tracking technology. All the tests are done in a single visit, with an estimated duration of 1-1.5 hours.

What are the possible benefits and risks of participating?
The anticipated benefit of the study will be the development and validation of a digital test to assess visual function in children from 6 months of age, by means of a portable device which does not require special training to be used. There are no risks in participating. All of the exams of the clinical protocol are non-invasive and innocuous.

Where is the study run from?
Coordinating center: Miguel Servet University Hospital, Zaragoza, Spain
Recruiting centres are currently being confirmed

When is the study starting and how long is it expected to run for?
November 2018 to May 2020

Who is funding the study?
Huawei Technologies Co. (China)

Who is the main contact?
Dr Victoria Pueyo
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Study website
https://dive-medical.com/TrackAI.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PI18/346

Study information

Scientific Title
Implementation of artificial intelligence for the detection of visual dysfunction in childhood

Acronym
TrackAI Project

Study objectives
Children with visual disorders can be identified from children with a normally developed visual function using a digital test including different visual stimuli implemented in a DIVE, by means of a neural network.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/01/2019, local ethics committee (Comité Ético en Investigación Clínica de Aragón, CEICA, San Juan Bosco 13, 50009 Zaragoza, Spain), Project code: PI18/346

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not yet available in web format. Please use contact details to request participation sheet.

Health condition(s) or problem(s) studied
Visual dysfunction

Interventions
All the included participants will undergo a complete ophthalmologic assessment and an exam of visual functions with a novel digital test. The novel digital device (DIVE) consists of a high-resolution screen assisted with eye-tracking technology. The child is positioned in front of the screen and, during 7-10 minutes, different stimuli are presented, while the eye-tracking registers his/her gaze positions. The test has monocular and binocular assessments, and examines several aspects of the visual function. All the clinical protocols will be done in a single visit, with an estimated duration of 1-1.5 hours. All the parameters are measured at baseline, since the study does not include any follow-up.

Intervention Type
Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
Global visual development (normal/abnormal), defined by the ophthalmologist based on their clinical assessments at baseline

Secondary outcome measures
All the following outcomes will be assessed for the right eye, for the left eye and for both eyes at baseline:
1. Oculomotor control: fixation stability, saccadic reaction time, saccadic accuracy, smooth pursuit accuracy, assessed using the DIVE device
2. Grating visual acuity, assessed using the DIVE device
3. Contrast sensitivity, assessed using the DIVE device
4. Colour perception: deutan, protan and tritan axes, assessed using the DIVE device
5. Ophthalmic diagnosis provided by the ophthalmologist based on their clinical assessments

Overall study start date
01/11/2018

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Age between 6 months and 14 years
2. Visual fixation stable enough to allow attentive fixation on the Lang cube
3. Assessments performed for all the following visual outcomes (although in some cases information may not be obtained):
3.1. External examination and red reflex
3.2. Visual acuity
3.3. Ocular motility
3.4. Refraction under cycloplegia
3.5. Funduscopy
4. Informed consent signed by parents or guardians of the child

Participant type(s)
Mixed

Age group
Child

Lower age limit
6 Months

Upper age limit
14 Years

Sex
Both

Target number of participants
5,000

Total final enrolment
2208

Key exclusion criteria
1. Previous ocular, muscular or orbital surgery. Since the main goal of the project is to develop a screening tool to identify children with abnormal visual development, children with any ocular or periocular surgery will be excluded from the study. However, children previously treated with optical correction, minor topic treatments or any therapy for amblyopia, will not be excluded, due to pragmatic reasons. Laser or intravitreal treatment for retinopathy of prematurity will not exclude a child.
2. Bad general health state, which does not allow an examination with DIVE. Lack of collaboration for performing the clinical protocol or the visual exam with DIVE is not an exclusion criterion.

Date of first enrolment
01/03/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Spain

Study participating centre
Miguel Servet University Hospital
Pso. Isabel la Catolica, 3
Zaragoza
Spain
50009

Sponsor information

Organisation
Fundación Instituto de Investigación Sanitaria de Aragón (IIS Aragón)

Sponsor details

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Sponsor type
Research organisation

Website
http://www.iisaragon.es

ROR
https://ror.org/03njn4610

Funder(s)

Funder type
Industry

Funder Name
Huawei Technologies

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
China

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals.

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan

The dataset generated during the current study will be stored in a non-publically available repository in Google Cloud Storage. Data will be automatically uploaded from each recruitment center, and downloaded for analysis at the coordinating unit. Patient data will be anonymized (i. e. personal information from patients will not be included in the dataset), the researchers will have a signed consent form for every patient, and everyone in charge of handling the data will sign an NDA. The analysis of the dataset is divided into two stages: data auditing and data usage. The data auditing stage is designed to guarantee that the protocol is being followed consistently and that all collected data is free of errors. It consists of a thorough automatic analysis performed with custom Python code, manual revision of automatically detected potential issues in collected data, and random revision of patient data from every recruitment center. During the data usage stage, the researchers use the collected data to train an artificial intelligence algorithm in order to estimate the probability for a patient to have a certain specific visual disorder.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/02/2020	15/01/2021	Yes	No
Results article		31/12/2022	14/06/2023	Yes	No