ISRCTN53630869 https://doi.org/10.1186/ISRCTN53630869

Use of a smartphone camera to assess pupil response to light in neurocritical care – comparison with pen torch

Submission date 23/02/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 20/04/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/04/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is designed to compare the accuracy of measuring eye pupil size. It will compare the current standard of care, which is a pentorch and subjective assessment by a bedside nurse, to a new smartphone application using the camera and light of the phone to measure pupil size and responsiveness.

Who can participate?
Patients admitted to a specialist neurocritical care unit

What does the study involve?
Participants will have their pupils assessed by both methods hourly (which is standard) for a maximum of 10 days, during the day only. Not measuring at night provides respite for the patient (they will still have pentorch assessments) and reduces research staffing resources.

What are the possible benefits and risks of participating?
The interventions are non-invasive and as such there are no risks to participants. The proposed benefit is earlier identification of changes in pupil response, both in terms of improvement and deterioration.

Where is the study run from?
John Radcliffe Hospital (UK)

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

Who is funding the study?
Solvemed Inc. (UK)

Who is the main contact?
Dr Simon Raby, simon.raby@ouh.nhs.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
324539

Study information

Scientific Title
Smartphone Pupillometry in Neurocritical Care - Comparison against PenTorch: the SPIN_CAT trial

Acronym
SPIN-CAT

Study objectives
Smartphone pupillometry is more accurate than pentorch assessment of pupil responsiveness in neurocritical care patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, South Central - Oxford C REC

Primary study design
Interventional

Study design
Single-centre non-randomized trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Critically ill patients admitted to neurocritical care

Interventions
Patients will have pupillary assessments made by pentorch and smartphone pupillometry. Pentorch is routine and the smartphone application is the additional intervention. Each intervention will be performed hourly during the day shift, for a maximum of 10 days per patient.

Pupil traces will be processed by Solvemed to generate two indices per eye: baseline pupil diameter (millimetres), and pupil reactivity (binary – responsive or non-responsive). Measurement reliability for pentorch and Solvemed app (baseline diameter) will be computed independently, to give an r-squared statistic for each. The reliabilities will be compared using a Fisher-transformed Z-test. The validity of the app will be established by the correlation of the pentorch and app measures. The primary outcome is that the app offers improved reliability. To gauge efficiency, questionnaires to nursing staff will be analysed using qualitative nonparametric statistics.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
Solvemed Neurapeek

Primary outcome(s)
Pupil diameter (millimetres) and pupil reactivity (binary – responsive or non-responsive) measured using the two modalities (pentorch and Solvemed smartphone application), performed hourly during the day shift, for a maximum of 10 days per patient

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/04/2023

Eligibility

Key inclusion criteria
Any patient admitted to neurocritical care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Pupillary assessment not possible due to ocular pathology

Date of first enrolment
01/04/2023

Date of final enrolment
01/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford Radcliffe Hospital NHS Trust
The John Radcliffe
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Solvemed Inc.

Funder(s)

Funder type
Industry

Funder Name
Solvemed Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository: Following video capture, the video is uploaded onto the company-owned Amazon S3 server storage space (the cloud storage), where the captured videos and any associated data are stored in Amazon SQL databases. To ensure the stored data is secure, company applies an industry-standard Hypertext Transfer Protocol Secure (HTTPS) encryption protocol for all traffic between its smartphones and AWS servers. In addition, company applies suitable company-level policies regarding the access levels and procedures regarding every Amazon AWS component, using appropriate Amazon roles and Amazon policies.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	03/08/2022	07/03/2023	No	No