

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/04/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/04/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

324539

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Single-centre non-randomized trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/10/2022

Completion date

01/04/2023

Eligibility**Key inclusion criteria**

Any patient admitted to neurocritical care

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

20

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**

England

United Kingdom

Study participating centre

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

Sponsor information

Organisation

Solvemed Inc.

Sponsor details

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Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Solvemed Inc.

Results and Publications

Publication and dissemination plan

The study will be published in a high-impact peer-reviewed journal.

Intention to publish date

01/06/2023

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