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The continuous ambulatory vestibular assessment (CAVA) multicentre dizziness trial

Submission date
27/01/2023

Recruitment status
No longer recruiting

Registration date
31/01/2023

Overall study status
Completed

Last Edited
05/11/2025

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol
Background and study aims
Dizziness is common and identifying the condition causing it is challenging. This can lead to patients experiencing significant delays in diagnosis. The aim of this study is to test the CAVA system's ability to use eye movement data collected by the device to diagnose dizziness conditions. This could greatly reduce the time to diagnosis saving the NHS money by reducing multiple visits to GP clinics, referrals to specialists and the number of treatments required.

Who can participate?
Adults who have been diagnosed with Meniere's disease, vestibular migraine or benign paroxysmal positional vertigo (BPPV) and currently experiencing episodes of vertigo/dizziness.

What does the study involve?
The study involves wearing a device that goes over the ear and attaches to the face for 30 consecutive days whilst logging dizziness symptoms in a diary. There will be up to five in-person hospital visits to learn how to use the device and complete questionnaires.

What are the possible benefits and risks of participating?
Benefits include helping conduct the research around identifying dizziness conditions using the CAVA device. Risks include some redness caused by the electrode pads attaching to the skin.

Where is the study run from?
The study is run from the Norfolk and Norwich University Hospital and the University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
July 2022 to October 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Gregory M Howard, Gregory.howard@uea.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
317899

Central Portfolio Management System (CPMS)
54262

Study information

Scientific Title
Continuous ambulatory vestibular assessment (CAVA) - development of a system to provide an automatic diagnosis for vestibular conditions

Acronym
CAVA

Study objectives
The CAVA System will identify and differentiate nystagmus using the algorithm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/10/2022, West Midlands – South Birmingham REC (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8345, +44 (0)207 104 8068, +44 (0)207 104 8143; southbirmingham.rec@hra.nhs.uk), ref: 22/WM/0229

Primary study design
Interventional

Study design
Non-randomized; Both; Design type: Diagnosis, Device, Validation of outcome measures

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vestibular conditions

Interventions
All participants fulfilling the eligibility criteria and providing consent will wear the CAVA device for 30 days in a real-world context. Then the CAVA algorithm will diagnose each patient based only on the data recorded from the device. The accuracy of the system will be tested by comparing the CAVA system's diagnosis with each patient's known diagnosis.

All participants will be provided with the PIS after confirmation of eligibility at Visit 1. They will receive training on how to wear the monitoring device and how to use and care for it at the hospital at Visit 2 (Day 0). Once competency in the use of the CAVA system is demonstrated participants will be asked to wear the device for 30 consecutive days, 23 hours each day. At Visit 3 (Day 5) participants will return to the hospital to assess adherence and adverse reactions. The battery will need to be replaced around halfway through the 30 days so participants will return to the hospital for Visit 4 (Day 15) to have the battery changed, assess adherence and adverse events. Also at Visit 4 any participants with benign paroxysmal positional vertigo (BPPV) will receive treatment whilst wearing the device. The participants will return to the hospital for Visit 5 (Day 33) to return the device and all accessories as well as complete a questionnaire.

Participants will replace the electrode pads on a daily basis during their participation. The device has an 'event marker' button to be used when a patient experiences dizziness. The patient would

press this button to effectively mark the data denoting an episode of dizziness. Support and advice will be provided by the research team to deal with any concerns which arise from using the CAVA system.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
Identification of nystagmus data from the device using a computer algorithm; data is collected during the 30 days wearing the device

Key secondary outcome(s)
1. Safety events assessed using adverse event (AE) reporting on Day 5, Day 15, Day 33
2. Health economics measured using a bespoke health economic questionnaire, Social life & Work Impact of Dizziness (SWID) questionnaire and EQ5D3L on Day 0, Day 5, Day 15, Day 33
3. Average time to first dizzy attack determined using device and diary data collected during the 30 days
4. Device compliance measured using device data collected during the 30 days
5. Patient acceptability measured using a tailored user experience questionnaire on Day 33 or at end of participation if earlier
6. Device malfunctions assessed using device data collected during the 30 days
7. Commercialisation informed using the health economics data (post data collection analysis)

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Age 18 years and over
2. Must have relevant index medical condition: Ménière’s disease, vestibular migraine, posterior canal benign paroxysmal positional vertigo
3. Experiencing episodes of true vertigo with at least two episodes within the preceding 4 weeks at time of consent
4. The duration and nature of the vertigo is of a duration and a nature supportive of the relevant index medical condition
5. Owns and is able to use a telephone
6. Willing to provide informed consent
7. Willing to comply with the study protocol for using the CAVA device
8. Willing to complete all study materials
9. Adequate grasp of the English language or language used within an existing translated version of the informed consent form and patient information sheet and where hospital translators are available to provide support

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
51

Key exclusion criteria
1. Has an allergy to plasters and/or medical adhesives
2. Evidence of dermatitis, fragile skin, or any other condition that could be aggravated by the repeated application of skin surface adhesives
3. Pregnant or breastfeeding mothers
4. Bilateral or second side Ménière's disease
5. Active bilateral or second side posterior canal benign paroxysmal positional vertigo
6. Currently enrolled on an intervention trial (not including questionnaire-based or observational trial)
7. Patients who meet diagnostic criteria for more than one eligible condition at time of recruitment

Date of first enrolment
21/02/2023

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
St Georges Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

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Colney Lane
Colney
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Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre

University Hospital Birmingham
Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Gloucester Royal Hospital
Great Western Road
Gloucester
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GL1 3NN

Study participating centre
Southend University Hospital
Prittlewell Chase
Westcliff-on-sea
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SS0 0RY

Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust

ROR
https://ror.org/01wspv808

Funder(s)

Funder type

Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202870

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		07/11/2024	20/11/2024	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes