# VERTIGO Trial vs. Tele-Dizzy

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Summary of key differences and similarities between the VERTIGO trial and Tele-Dizzy.

*The main differences are that the VERTIGO trial randomizes the timing of implementing Tele-Dizzy, patient eligibility is more tightly managed, and structured data need to be captured in follow-up.*

| | VERTIGO Trial to Study Tele-Dizzy | PARAMETER | Clinical Tele-Dizzy Service |
|---|---|---|---|
| Foundational Differences | Hybrid Research (clinical trials) & Operations (clinical care) | **Overall Program Type** | Operations (clinical care) |
| | Yes | **Clinical Trial** | No |
| | JHM sIRB (reliance agreement required) / PCORI / DSMB / CT.gov / etc. & Local Office of Telemedicine / Legal / ED | **Regulatory Oversight** | JHM Office of Telemedicine / Legal / ED |
| | Yes (cluster, stepped wedge design) | **Randomization** | No |
| Major Differences | JHM sIRB (reliance agreement required) [follow-up consent for patients will be via mobile app and will occur post ED visit; local telemedicine rules apply for any additional consent required] | **Consent Required** | JHM Office of Telemedicine / ED (standard telemedicine consent) |
| | ~27 hospital EDs around the US affiliated with ~6 hubs, potentially includes JHM sites<br>**NOTE: EDs already running Tele-Dizzy cannot join the VERTIGO trial** | **Sites Involved** | JHM (JHH or other adult JHM EDs);<br>Outside JHM: any hospital willing to contract for the service with JHM (e.g., Allegheny General Hospital) |
| | JHM neuro-otologists (including potentially fellows or APPs prior to clinical attending review) **OR certified local clinicians (neurology or EM)** | **Interpretation of Results** | JHM neuro-otologists (including potentially fellows or APPs prior to clinical attending review) |
| | Site bills independently for testing; **JHM delegates billing, paid per consult OR routine billing if locally interpreted** | **Billing / Finance** | Site bills independently for testing; JHM clinicians bill directly for interpretation |
| Similarities | ICS® Impulse - VOG running Otosuite software package (FDA approved) | **VOG Goggles Used** | ICS® Impulse - VOG running Otosuite software package (FDA approved) |
| | Nurses or other clinical staff | **Testing Personnel** | Nurses or other clinical staff |
| | Tele-Dizzy software v2.0 (web-based, standard installer; local enterprise authentication is used at each site) | **Data Collection Tools** | Tele-Dizzy software v2.0 (web-based, standard installer; local enterprise authentication is used at each site) |
| | As needed / available (e.g., Epic) | **Direct Patient Video** | As needed / available (e.g., Epic) |
| Minor Difference | JHM-managed Microsoft Azure instance (single PCORI-specific server for patients from all 27 sites) | **Data Warehouse** | JHM-managed Microsoft Azure instance (site-specific server for each health system / discrete entity) |

**Why Tele-Dizzy is <u>not</u> research even though the VERTIGO trial <u>is</u> research:**

The process of experts using eye movements to diagnose and differentiate ear diseases from stroke in the emergency department (ED) is well-established in the medical literature and outperforms even MRI neuroimaging in the acute phase.[1-6] By contrast, current standard of care routine ED practice is poor for diagnosing stroke in dizzy patients, with tens of thousands of stroke patients misdiagnosed annually in the US, and hundreds of thousands with inner ear diseases given wrong diagnoses and treatments.[7-12]

The video-oculography (VOG) technology used is FDA-approved and is currently in routine clinical use with human interpretation by neuro-otology experts. Tele-Dizzy uses store forward to digitally transfer the video images to the reader (and would be paired with video teleconsultation, as necessary). It is fundamentally no different than remote reading of fundus photos or radiographic images. It is standard expert clinical care provided by a remote means. Quality of image acquisition is monitored to ensure adequate testing is maintained, but this is no different than with tele-fundus photos or radiographs acquired remotely. Because there are video images of the room and eye, traces of the eye and head, and time-synchronized playback of the entire test result, monitoring quality is straightforward.

The VERTIGO Trial is designed to assess if diagnostic care based on clinical VOG interpretation (whether by remote experts or locally trained personnel) is superior to imaging-based diagnosis on diagnostic accuracy, diagnostic test utilization / ED length-of-stay, and health outcomes for patients with acute dizziness or vertigo in the ED. **Thus, the VERTIGO trial is a research study assessing the <u>impact</u> of implementing clinical Tele-Dizzy. In the stepped wedge VERTIGO trial, sites will transition from imaging-based diagnosis (trial Epoch #1) to VOG-based diagnosis (trial Epoch #2).** Since each care pathway will be designated as standard care at the time it is being given (i.e., there will be no patient-level randomization), consent will only be required for post-ED follow-up, done by mobile phone.

**Summary**

In summary, the foundation for Tele-Dizzy as a clinical service is well established scientifically—experts can diagnose patients on the basis of eye movements even better than our currently available "gold standard" (MRI with diffusion-weighted imaging).[13] Because the standard of care in the ED is that experts are not available, and current ED "standard care" practice demonstrates a massive evidence-practice gap,[10,11] providing access to expert interpretation of eye movements via Tele-Dizzy as a clinical service is ethical, appropriate, and supported by scientific evidence as a quality improvement initiative. The VERTIGO trial will measure the impact of that quality improvement initiative via a large, pragmatic, comparative effectiveness trial of imaging vs. VOG/teleconsultation using a stepped wedge design.

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