

NASA	PROSPECTIVE OBSERVATIONAL STUDY OF OCULAR HEALTH IN ISS CREWS	OCULAR HEALTH
Principal Investigator		
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Description		
<p>The International Space Station (ISS) Ocular Surveillance Protocol aims to systematically gather physiological data to characterize the Risk of Microgravity-Induced Visual Impairment/Intracranial Pressure on crewmembers assigned to a 6 month ISS increment. The data collected will mirror Medical Requirements Integration Documents (MRID) requirements and testing performed during annual medical exams. The frequency of in-flight and postflight testing will be increased to more accurately assess changes that occur in the visual, vascular, and central nervous systems upon exposure to microgravity and induction of fluid shifting. Monitoring in-flight changes, in addition to postflight recovery, is the main focus of this protocol. A data sharing plan with Medical Operations will reduce redundancy of data acquisition. Preflight, in-flight and postflight measures include: tonometry, ocular ultrasound, fundoscopy, and visual acuity; while magnetic resonance imaging (MRI), optical coherence tomography (OCT), and bio-microscopy will be captured preflight and postflight exclusively. Two additional, non-MRID measures, blood pressure and cardiac output, will be collected preflight, in-flight and postflight to assess vascular compliance. Data collection will begin one year prior to flight, continue in-flight approximately every 30 days, and through to one year postflight. In circumstances where abnormalities may persist beyond one year, postflight data will continue to be collected, but as per the MRID requirements (MedB 1.10) and Visual Impairment/Intracranial Pressure (VIIP) clinical practice guidelines.</p>		
Objectives		
<ol style="list-style-type: none"> 1. Characterize the nature of in-flight visual, vascular, and central nervous system changes during six months exposure to microgravity. 2. Document changes from pre- to postflight. 3. Document changes post-flight, including the postflight time course for recovery to baseline. 		
Relevance		
<ol style="list-style-type: none"> 1. An understanding of the etiology of the VIIP syndrome (from this study) plus a set of effective countermeasures (future studies) will be needed to mitigate the risk of visual impairment for extended duration missions especially if there is a dose response to spaceflight exposure, as suspected. 2. Patients suffering from Idiopathic Intracranial Hypertension (IIH) are likely to benefit from NASA's research of the VIIP syndrome and the increased focus on non-invasive measurement techniques since VIIP highly mimics the effects seen in IIH. 		
BDC Summary		
<p>The data collected will mirror MRID requirements and testing performed during annual medical exams; however, two additional tests will be performed and the frequency of postflight testing will be increased to more accurately assess changes that occur in the visual, vascular, and central nervous systems. The preflight MRID required tests are an MRI at launch minus (L-) 21-18 months; Ocular Ultrasound at L- 12-9 months, L- 9-6 months, and L- 6-3 months; Fundoscopy, IOP (Tonometry), Visual Acuity, Amsler Grid, OCT, A-Scan, and Biomicroscopy and Hi-Res Photography at L- 21-18 months and L-9-6 months. The two tests that will be done in addition to MRID requirements are Blood Pressure for IOP (Tonometry) at L- 21-18 months and L- 9-6 months, and Vascular Compliance (Cardiac Ultrasound and Blood Pressure) at L- 9-6 months. The postflight MRID required tests are an MRI, Ocular Ultrasound, Fundoscopy, IOP (Tonometry), Visual Acuity, Amsler Grid, OCT, A-Scan, and Biomicroscopy and Hi-Res Photography at return plus (R+) 1-3. In addition to these MRID requirements, Blood Pressure for IOP (Tonometry) and Vascular Compliance (Cardiac Ultrasound and Blood Pressure) will also be done on R+1-3 and the entire suite of tests will be done at R+30, R+90, R+180, and R+360.</p>		
In-flight Operations Summary		
<p>In-flight, the data collected will mirror MRID requirements; however, two additional tests will be performed and the frequency of in-flight testing will be increased to more accurately assess changes that occur in the visual, vascular, and central nervous systems. Due to time constraints, each scheduled test day will be split into two days (Day A & Day B) that can either be consecutive or separated by 1 intervening day. The in-flight MRID required tests are Ocular Ultrasound, Fundoscopy, and IOP (Tonometry) on flight day (FD) 30 and return minus (R-) 30, and Visual Acuity and Amsler Grid on FD 30, FD 100, and R-30. In addition to these MRID requirements, these tests will also be conducted on FD 10, FD 60, FD 90, and FD 120. The two additional tests, Blood Pressure for IOP/Tonometry and Vascular Compliance (Cardiac Ultrasound and Blood Pressure), will be conducted on FD 10, FD 30, FD 60, FD 90, FD 120, and R-30.</p>		
Subject Selection/Participation Criteria		