

Objective: Define successive bed rest campaigns leading to a potential VIIP countermeasure

To determine if the analog is successful, changes need to occur in following **outcome measures** (dependent variables):

- Intracranial pressure
- Retinal nerve fiber layer
- Choroidal engorgement
- Globe flattening
- Axial biometry
- Optic nerve sheath diameter distention
- Cycloplegic refraction
- Visual acuity

Study parameters (independent variables) to include:

- CO₂
- Sodium
- Exercise (resistive & aerobic)
- Strict tilt angle

What information can the currently defined studies provide?

- Karina/Joerne enVIIP: $\angle 6^\circ$, 12° , 18° + eye changes; $\angle 12^\circ$ w/ 1% CO₂; $\angle 12^\circ$ + LBNP
- Vascular Compliance: Compares effects of more and less compliance
 - VIIP strongly prefers to add CO₂ to Vascular Compliance
- Vizzeri/Laurie: 1 hour with 1% CO₂ at $\angle 6^\circ$
 - VIIP prefers to add 2 compliance groups and longer duration
- Scott: Effects of exercise modalities at $\angle 15^\circ$
- NSBRI Pilot – Confirms facility capabilities for CO₂ administration, etc. Defines tilt $\angle$.
 - VIIP prefers to do multiple tilts $\angle 6^\circ$, 9° , 12° with 2 compliance groups (unless another study identifies optimum angle e.g. 9 degrees)

Pilot CO2



Expected study parameters:

- 24 hours at $\angle 6^\circ$ Head Down Tilt (HDT)
- CO₂ at 0.5% - 1%
- Data collection mirrors ISS Ocular Health
- Prefer 2 Compliance groups
- Sodium levels ??
- N = ??

Assumptions:

- NSBRI sponsored
- Studies completed before this campaign begins:
 - Karina/Joern enVIIP: 5 hrs. at enviHab
- Location: enviHab

Acute CO₂



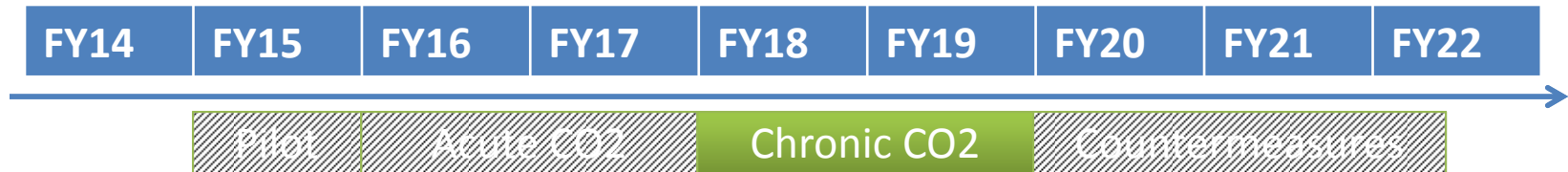
Preferred Study parameters:

- 5 - 7 days at $\angle 12^\circ$ HDT or 7 - 10 days at $\angle 9^\circ$ HDT or 10 - 14 days at $\angle 6^\circ$ HDT
(the tilt angle and duration should be defined by previous studies and what elicits VIIP related change)
- CO₂ at 0.5% - 1% depending on duration and safety
- 2 compliance groups – high (females) and low
- Sodium levels similar to ISS (fixed/constrained)
- N = ?

Assumptions:

- Studies completed before this campaign begins:
 - Karina Bowman / Joern Rittweger 5 hrs. at envihab
 - NSBRI Pilot 24-hour with CO2 at envihab
 - Vascular Compliance bedrest at UTMB
 - J. Scott Exercise at JSC
- Location: envihab
- Year 1 – planning, definition, approvals, pilot.
- Year 2 - Implementation

Chronic CO₂



Study parameters:

- ∠ tbd° Head Down Tilt (HDT) depending on results of Acute study
- Duration: Extended from Acute CO₂ study to ~ 1 month
- CO₂ at 0.5% - 1.0% depending on duration and safety
- 2 compliance groups – high (females) and low
- Sodium levels similar to ISS (fixed/constrained)
- Exercise – resistive (or resistive AND aerobic like ISS)
- N = ?

Assumptions:

- Studies completed before this campaign begins:
 - Acute CO₂ at envHab
 - Mechanical Countermeasures NRA14
 - J. Scott - Exercise
- Location: envHab
- Year 1 – planning, definition, approvals, pilot.
- Year 2 - Implementation

Countermeasures Validation



Study parameters:

- CO₂ (fixed)
- Tilt (fixed)
- Sodium similar to ISS (fixed)

Countermeasures to be tested

- Mechanical device
- Exercise modalities
- Pharm (only if no mechanical CM has proven effective)

Assumptions:

- Studies completed before this campaign begins:
 - Acute & Chronic CO2 at envihab
 - Mechanical Countermeasures NRA14
 - J. Scott – Exercise
- Location: envihab