

# Growth Hormone Replacement Therapy in Veterans With Mild Traumatic Brain Injury (mTBI) and Adult Growth Hormone Deficiency (AGHD)

NCT04867317

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 3
<b>Sponsor</b>	VA Office of Research and Development
<b>Enrollment</b>	172 participants

## Key Eligibility Criteria

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### Inclusion (9)

- OEF/OIF/OND Veteran
- Score of 18 or more on Combat Experiences sub-scale of Deployment Risk and Resilience Inventory-2 (DRRI-2)
- Age 21 - 55 years old
- One or more mTBI sustained during military service at least 12 months prior to the screening date, as noted via the CRAFT survey
- GH deficiency diagnosed by: macimorelin stimulation test (cut point 5.1 mcg/L) and IGF-I lab values have to be less than or equal to +1 SDS at baseline
- ... and 4 more (see full listing online)

### Exclusion (14)

- History of moderate or severe TBI
- History of neurologic disorder other than TBI with substantial impact on quality of life
- History of bipolar disorder, schizophrenia, or other concurrent psychotic disorder
- Active suicidal ideation (no plan required) as determined by a score of 2 points or more on the Columbia Suicide Severity Rating Scale (C-SSRS) suicidal ideation rating, or overt suicidal behavior in the past 6 months
- Contraindication to rhGH therapy
- ... and 9 more (see full listing online)

## Locations (4 total)

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Atlanta VA Medical and Rehab Center, Decatur, GA, Decatur, Georgia, United States  
Minneapolis VA Health Care System, Minneapolis, MN, Minneapolis, Minnesota, United States  
Michael E. DeBakey VA Medical Center, Houston, TX, Houston, Texas, United States  
... and 1 more locations