



The UCSD Dynamic Metabolomic Analysis (DMA) Study

University of California, San Diego School of Medicine
July 18, 2019

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

Inclusion Criteria

1. Females, at least 18 years old
2. Meet the diagnostic criteria for ME/CFS. These are:
 - a. Life altering fatigue for more than 6 months
 - b. Post-exertional malaise
 - c. Non-refreshing sleep
 - d. At least one of the following:
 - i. Episodes of brain fog
 - ii. Postural orthostatic tachycardia syndrome (POTS)
3. Stable diet and medication regimen for at least 2 months
4. No plans to change diet or medication during the month of the study
5. Mobile and able to communicate with study personnel

Exclusion Criteria

1. Meet DSM-5 diagnostic criteria for major depressive disorder (F32, F33), bipolar disorder (F31), or schizophrenia (F20.9)
2. Pregnancy, or planned pregnancy
3. Hospitalization in the past 2 months
4. An acute infection, trauma, or other serious injury in the past 3 weeks
5. Any active medical problems such as unstable seizures, significant heart, liver, kidney, or adrenal disease, or acute infection (eg, URI, "cold", "flu", "strep")
6. Live more than a 2-hour drive from Dr. Naviaux's lab in San Diego
7. Unable to tolerate the planned, routine blood draws (1 teaspoon x 4 over 1 month)

Study Description

1. Check to see if you meet the inclusion and exclusion criteria
2. Read the informed consent (Project #140072) and ask any questions you like.
3. Contact our Study Coordinator, Rachel Riggs, by email (rriggs@ucsd.edu) or cell phone: (619) 884-8021, for any questions.
4. Sign the consent and keep a copy for your records along with a copy of the "Experimental Subject's Bill of Rights"
5. Complete the 1-page "Basic Data" page
6. Complete the SF36 and GSQ-30 questionnaires
7. Have a teaspoon of blood drawn each week (\pm 2 days) for 4 weeks
8. That's it.

Post-treatment Lyme Disease Syndrome (PTLDS)

Inclusion Criteria

1. Females, at least 18 years old
2. Meet the diagnostic criteria for PTLDS. These are:
 - a. Documented Lyme disease by two-tier testing; 1) positive EIA or IFA, followed by 2) a positive Western blot, with or without the erythema migrans (EM) rash, treated with doxycycline for 4 weeks
 - b. Life altering fatigue for at least 6 months after completing antibiotic treatment
 - c. Three or more areas of musculoskeletal pain
 - d. Brain fog, difficulty finding words, difficulty with routine memory tasks
3. Stable diet and medication regimen for at least 2 months
4. No plans to change diet or medication during the month of the study
5. Mobile and able to communicate with study personnel

Exclusion Criteria

1. Meet DSM-5 diagnostic criteria for major depressive disorder (F32, F33), bipolar disorder (F31), or schizophrenia (F20.9)
2. Active co-infection with Babesia, Bartonella, Ehrlichia, Anaplasma, or similar, as evidenced by low WBC, low platelets, or elevated liver function tests (LFTs).
3. Diagnosis of fibromyalgia or chronic fatigue syndrome before the diagnosis of Lyme disease
4. Musculoskeletal pain or fatigue before the diagnosis of Lyme disease
5. Pregnancy, or planned pregnancy
6. Hospitalization in the past 2 months
7. An acute infection, trauma, or other serious injury in the past 3 weeks
8. Any active medical problems such as unstable seizures, significant heart, liver, kidney, or adrenal disease, or acute infection (eg, URI, "cold", "flu", "strep")
9. Live more than a 2-hour drive from Dr. Naviaux's lab in San Diego
10. Unable to tolerate the planned, routine blood draws (1 teaspoon x 4 over 1 month)

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Healthy Control Subjects

Inclusion Criteria

1. Healthy females, at least 18 years old
2. No chronic illness, and not taking any prescription medicines for a chronic illness
3. Stable diet, supplement, and activity or exercise regimen for at least 2 months
4. No plans to change diet, supplement, or exercise regimen during the month of the study

Exclusion Criteria

1. Pregnancy, or planned pregnancy
2. Hospitalization in the past 2 months
3. An acute infection, trauma, or other serious injury in the past 3 weeks
4. Any active medical problems such as unstable seizures, significant heart, liver, kidney, or adrenal disease, or acute infection (eg, URI, "cold", "flu", "strep")
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What we hope to learn

Although we will not be able to return any personalized results to you after this study, we hope that by analyzing the results from all the participants we will be able to learn how dynamic factors in the body play a role in maintaining chronic illness, and prevent the healing process. This work will pave the way for a new clinical trial of a drug that works by unblocking the healing cycle, so that a person with a chronic illness can restart the active healing process, and get back on the road to recovery.