

Study Background

The National Institutes of Environmental Health Sciences (NIEHS) is conducting a randomized controlled clinical trial that will examine the effects of omega-3 fatty acid (O3FA) supplementation, along with a study diet that follows a healthy diet pattern. The study is designed to test if fish oil will decrease dermatomyositis and increase muscle strength. As part of this study, patients will receive dietary coaching and take 4 fish oil or placebo softgel capsules twice a day over 9 months. The study will take place at the NIH Clinical Center in Bethesda, Maryland.



The NIH Clinical Center (pictured above) contains around 200 inpatient beds and has 93 day-hospital stations. There are over 2,000 credentialed physicians, nurses, researchers, and other health-care professionals working at the NIH.

Enrollment Criteria

To participate you must meet several enrollment criteria. Here are some of the key qualifications:

Inclusion criteria are individuals with:

- Subjects must be adults 18-60 years old
- A diagnosis of juvenile or adult dermatomyositis that is currently active
- Willingness to take study supplement twice a day for 24 weeks
- Willingness to adhere to the study diet and undergo dietary coaching
- Ability to read English and access the internet for completing questionnaires and viewing diet coaching materials and videos.
- Participate in 5 study visits at the NIH Clinical Center in Bethesda, Maryland

Exclusion criteria would be patients who:

- Are pregnant or breastfeeding
- Have certain known food allergies
- Are using O3FAs or taking EPA/DHA in any form in the past 6 months
- Have other forms of myositis such as: polymyositis, inclusion body myositis, and cancer-associated myositis

To view all criteria, visit: <https://clinicaltrials.gov>

PRE-TREATMENT



Screening Visit

- The first visit is to confirm eligibility
- This visit may last 1 to 4 days and occurs at the NIH Clinical Center

Pre-Treatment Assessment

- If eligible, enroll into the study and establish a baseline of your disease activity
- This visit lasts up to 5 days at the NIH Clinical Center
- Complete study assessments*

TREATMENT



Baseline and Start of Study Treatment

- This visit lasts up to 6 days at the NIH Clinical Center
- Complete study assessments*
- Start study drug (O3FA or placebo)
- Start the study diet with dietary coaching: that includes reviewing materials online and watching videos about diet.

On-Treatment Assessment

- 12 weeks after treatment starts, your dermatomyositis disease activity will be reassessed compared to your baseline
- Complete study assessments*

Study Activities at Home

- Take study drug twice daily and log with any side effects
- Review dietary education materials, attend office hours, and follow study diet
- Telehealth check-ins at weeks 6 and 18, with online questionnaires
- Wear activity tracker wristwatch for 7 days at weeks -1 and 23

END OF STUDY



End of Study Treatment

- 24 weeks after study treatment initiation
- Visit lasts up to 6 days at the NIH
- End study drug or can continue into open-label extension
- End dietary coaching at week 19
- Complete study assessments*

Optional Open Label Extension

- If a participant continues into the open label extension, they will progress on in the study for 12 more weeks.
- Everyone will receive O3FA and continue the study diet
- No dietary coaching
- Week 30 is a telehealth visit
- Week 36 is the final study visit
- Complete study assessments*

End of Study Participation

- After 30 or 42 weeks from pre-treatment assessments, your participation is complete. Reimbursement is offered throughout the study.

The total length of the study, from your Pre-Treatment Assessments to your last visit, is 30 or 42 weeks. Some visits occur at the NIH Clinical Center, while others occur remotely.



*Study Assessments include:

- Physical Exams
- Online Questionnaires completed by Patient and Physician
- Diet Recalls
- Blood, urine, and stool testing
- Imaging studies, including MRIs, DEXA scans, and vascular imaging
- EKG, heart echocardiogram, and breathing tests
- Visits with medical specialists, such as physical therapy and dieticians

Diet and Autoimmune Disease

Your diet may impact the management and progression of autoimmune diseases. Certain foods can reduce or worsen inflammation and immune responses. For example, a diet rich in anti-inflammatory foods like fruits, vegetables, whole grains, and healthy fats (such as omega-3 fatty acids) may potentially help reduce symptoms and flare-ups.



Conversely, foods high in sugar, unhealthy fats, and processed ingredients could potentially trigger inflammation and worsen autoimmune conditions. Therefore, tailoring your diet to include beneficial nutrients and avoid potential irritants may play a role in managing autoimmune disease symptoms.

Resources

NIEHS Website

<https://joinastudy.niehs.nih.gov>

Clinical Trial (NCT07111065)

<https://bit.ly/4neSQpK>

Discovery Channel Documentary on NIH Studies

<https://clinicalcenter.nih.gov/ocmr/firstinhuman>

Contact Information

NIH Clinical Center Office of Patient Recruitment

Toll Free: 1-800-411-1222

TTY for the deaf or hard of hearing: 1-866-411-1010

prpl@mail.cc.nih.gov

Se habla español

Study Team Contact information

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