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Journal of Immunology

ISSN 2995-861X

Research Article

Mycobacterium Smegmatis In The Treatment Of Fibromyalgia And Chronic Pain Via The Microbiome.

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Abstract

Fibromyalgia has received numerous definitions since an initial criteria was proposed by the American College of Rheumatology in 1990[1]. These definitions have since been modified but they always use a purely subjective definition: chronic, widespread, multi-site pain lasting for at least three months. In 2012, Behm, et al.,[2] identified objective diagnostic criteria for fibromyalgia with evidence of underlying immune system deficiencies in peripheral blood mononuclear cells and their inability to manufacture normal quantities of particular chemokines and cytokines. Subsequently, research by Mohapatra, et al.,[3] documented that 100% of fibromyalgia patients, based upon the Behm criteria, have unique DNA genomic signatures. A treatment protocol using heat-killed Mycobacteria smegmatis was conducted on 214 fibromyalgia blood test positive patients. This was an IRB-approved double-blind/placebo study. Those receiving the highest dose (of 250 mg per day) all had a reduction in symptoms except for those individuals who used neutropenic prescription medications.

Objective: We sought to identify a pathway to attenuate and/or eliminate the symptoms and presentations of fibromyalgia and chronic pain patients using an immune system stimulating compound. All of the fibromyalgia patient participants except a control group had a positive blood test score for fibromyalgia-related immune system deficiencies. We measured 11 different groups of fibromyalgia-associated symptoms in each individual. Patients were followed on a weekly basis for 30 days.

Methods: We studied 214 subjects. Of those, 8 made up a control group of non-fibromyalgia individuals. The remaining group all had proof of fibromyalgia-related immune system deficiencies based upon a diagnostic blood test developed at the University of Illinois College of Medicine at Chicago, Department of Pathology[2]. This test has been available since 2012 and to date, there has never been any evidence that this test is inaccurate. Indeed, in subsequent research published in 2024[3], 100% of all fibromyalgia blood test positive patients were found to have unique DNA genomic signatures. When compared to matched control patients who had tested negative through this blood test for fibromyalgia, none of these DNA genomic signatures were found in that group. Consequently, this test was based upon objective evidence of multi-studies demonstrating the objective blood test positive criteria for defining fibromyalgia. An independent study done by Wallace, et al.,[4] which was presented at the 2013 American College of Rheumatology Annual Convention, further delineated the accuracy of this blood test when it was completed in a separate laboratory facility. Based upon these quantifiable and proven blood test parameters, according to the blood test diagnostic criteria developed by Behm, et al., and subsequently proven as accurate by Wallace, et al., and which was substantiated by the DNA genomic signatures found in fibromyalgia test patients, we recruited fibromyalgia blood test positive individuals to evaluate the potential efficacy of Mycobacterium smegmatis in the treatment and potential elimination of fibromyalgia-related symptoms.Mycobacterium smegmatis was delivered as a heat-killed substance in a vegan capsule designed to not be absorbed until it reached the colon and the microbiome. The target of the M. smegmatis was the microbiome in the colon and the related gut-brain axis.

Conclusion: Patients taking a dose of 250 mg of Mycobacterium smegmatis on a daily basis experienced a 100% improvement in their fibromyalgia-related symptoms(including chronic pain) except for those individuals who failed to cease using immune system blocking and/or neutropenic prescription medications.

Keywords: Fibromyalgia; Chronic Pain; Mycobacterium smegmatis; Peripheral blood mononuclear cells; Microbiome; Gut-Brain Axis.

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Received: 18-July-2026, Manuscript No. JOI - 6021 **; Editor Assigned:** 20-July-2026 **; Reviewed:** 10-August-2026, QC No. JOI - 6021 **;**
Published: 19-August-2026, **DOI:** 10.52338/joi.2026.6021.
Citation: **Bruce Gillis.M.D.,MPH.** Mycobacterium Smegmatis In The Treatment Of Fibromyalgia And Chronic Pain Via The Microbiome.
Journal of Immunology. 2026 August; 18(1). doi: 10.52338/joi.2026.6021.
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INTRODUCTION

Since 1990, the American College of Rheumatology (ACR) has proposed a series of subjective diagnostic criteria for the definition of fibromyalgia. Those criteria were often seen to be in error and thus, they were steadily replaced. The current ACR fibromyalgia criteria though, remain based upon entirely subjective definitions. Additionally, these criteria actually overlap with numerous other chronic pain-related disorders as well as other overlying, related health problems including but not limited to the chronic fatigue syndrome, the irritable bowel syndrome, chronic insomnia, brain fog, mental depression and chronic anxiety.

MYCOBACTERIUM SMEGMATIS

Mycobacterium smegmatis was chosen based upon extensive research which has incorporated the use of a variety of microbiota. This included an analysis of the use of Mycobacterium obuense with an anti-cancer agent, Gemcitabine, in an effort to have a beneficial effect on the survival of patients with metastatic disease. As was noted in research published by Bazzi, et al.,[5] "the significant role played by Mycobacterium in modulating immune responses to enhancing the crosstalk between innate and adaptive immunity has been highlighted in several studies. Owing to their unique antigenic profile, heat-killed preparations of rapid-growing Mycobacteria, currently undergoing clinical development, has been assessed as adjuvant therapy in various diseases." We therefore analyzed the immune-modulating effects of a variety of Mycobacteria in the context of the peripheral blood mononuclear cells which were proven to be deficient in patients with fibromyalgia. These peripheral blood mononuclear cells were isolated from blood of both healthy individuals and those documented to have a positive fibromyalgia blood test score. The strains of Mycobacterium included M. agri, M. phlei, M. tokaiense, M. brumae, M. aurum, M. obuense and M. smegmatis. These were compared to a control compound, B. subtilis. The measured immune challenges were based upon measurements of fibromyalgia-related known chemokine and cytokine deficiencies of IL-6, IL-8, MIP-1 alpha and MIP-1 beta. The M. smegmatis was seen to be among the most effective in inducing peripheral blood mononuclear cell immune responses.[6] M. smegmatis acts on the microbiome of the colon. It functions as a nutraceutical via the Gut-Brain Axis and brain receptors.

A HISTORY OF FIBROMYALGIA

A summary regarding the understanding and definition of fibromyalgia was written by Bennett in 2004.[7] In it, Bennett conceded that the basis for fibromyalgia had been debatable. It had, in the past, been linked to a potential muscle disorder, an invented term of "central sensitization", the result of psychological factors or potentially attributable to an inflammatory disorder. Bennett conceded that the finding of fibromyalgia was a "classic example of a revised definition of disease," and the utilization of various definitions, such as "central sensitization" was a hypothetical "central amplification of sensory impulses." Bennett concluded that when it came to defining fibromyalgia "it resembles a moving target." It thus remained a subjectively defined disorder prior to the discoveries made by Behm, et al., and further verified by the breakthrough results of the genomic research completed by Mohapatra, et al.

SUBJECTS AND METHODS

We studied 214 individuals. Of this group, 8 individuals composed the Control Group. They had no chronic illnesses and had no evidence of fibromyalgia, either subjectively or per the fibromyalgia blood test which each one underwent. All 8 had negative fibromyalgia blood test scores. Of the remaining 206 individuals, these participants included a group of 157 females, ranging in age between 19-84 and 49 males, ranging in age between 34-74. The study was double-blind. The participants had a choice of five bottles to choose from. Dose 1 contained 1 mg of M. smegmatis per capsule. Dose 2 had 10 mg of M. smegmatis per capsule. Dose 3 had 100 mg of M. smegmatis per capsule. Dose 4 had 250 mg of M. smegmatis per capsule. Dose 5 had 0 mg of M. smegmatis per capsule and thus was the placebo dose. They received a 30-day supply of their dose.

Each participant completed and signed a questionnaire regarding their fibromyalgia-related symptoms before starting the trial and an IRB-approved consent form (Sterling IRB ID#8566-BS Gillis). In that questionnaire they had to respond to a series of questions. Every week they were asked to report the status of those symptoms.

Of the 206 participants, 7 did not complete the study. That left a total of 199 participants.

The questions that each individual had to respond to were as follows.

1. Have you experienced chronic or frequent areas of pain or tenderness prior to starting on the blinded dose of M. smegmatis? If so, how many times per week did you have those symptoms?
2. Prior to commencing your dose, have you experienced chronic or frequent fatigue or severe tiredness? If so, how many times per week have you experienced these symptoms?
3. Prior to commencing your dose, have you experienced frequent headaches and if so, how many times per week?
4. Do you have a history of any sleep-related issues?

Specifically, have you experienced any of the following prior to commencing your dose of M. smegmatis?

a. Trouble falling asleep?
b. Trouble staying asleep?
c. Trouble waking up after a night of sleep?
d. Are you sleeping less than 7-8 hours per night?
e. After sleeping and awakening, do you not feel refreshed?
f. Do you have sleep-related problems such that you require naps during the day?

5. Have you experienced any feelings or thoughts of depression, brain fog, mental confusion and/or memory problems prior to commencing on your specific dose? Please tell us which of these symptoms you have been experiencing and how often each week have you had these feelings.
6. Prior to commencing on your dose, have you experienced feelings of anxiety? How many days per week do you feel anxious?
7. Prior to commencing on your dose, have you been experiencing any of the following:
   Pelvic or lower abdominal pain?
   A sensation or a need to urinate frequently before commencing on the dose?
8. Prior to commencing on your dose, have you been experiencing episodes of abdominal pain, abdominal cramps, constipation, heartburn, nausea, vomiting or diarrhea? If so, identify how many of these symptoms you have been experiencing and how often you have been experiencing these symptoms each week prior to starting your dose.
9. Prior to starting your dose, have you been experiencing a lack of energy? If so, how many times per week have you had this problem?
10. Have you felt poorly or "crappy" prior to starting your dose? If so, how many times per week have you experienced these feelings?
11. List all prescription and non-prescription medications and supplements you are taking, and how many times per week do you take each?

This study was conducted under the auspices of the Sterling IRB (IRB ID#8566 BS Gillis). All of the participants had to read and sign a corresponding Informed Consent.

OUTCOME MEASURES

The symptom assessment was conducted both pre and post-treatment for the following conditions:

1. Chronic Pain/discomfort
2. Fatigue
3. Headaches
4. Poor Sleep
5. Feelings of Depression, Brain Fog, Mental Confusion and/or Memory Problems
6. Feelings of Anxiety
7. Pelvic discomfort/urinary frequency
8. Gastrointestinal/abdominal issues
9. Lack of energy
10. Persistent feelings of feeling poorly

The total number of initial participants per dose was as follows:

Dose 1 – 39 participants (33 females, 7 males); ranging in age of 25-76 with a mean of 55 years of age.

Dose 2 – 43 participants (34 females, 9 males); ranging in age of 28-81 with a mean of 57 years of age.

Dose 3 – 44 participants (27 females, 16 males); ranging in age of 30-77 with a mean of 55 years of age.

Dose 4 – 38 participants (27 females, 10 males); ranging in age of 19-71 with a mean of 54 years of age.

Dose 5 – 42 participants (35 females, 7 males); ranging in age of 22-84 with a mean of 56 years of age.

Participants completed questionnaires prior to engaging in the trial and during the trial they provided weekly assessments followed by a final questionnaire at the completion of the trial. The participants were asked the following questions:

1. Since using your dose, have you continued to experience chronic or frequent areas of pain or tenderness and if so, how often per week?
2. Since using your dose, have you continued to experience chronic or frequent fatigue or severe tiredness? If so, how often has this occurred each week?
3. Since using your dose, how often, if any, have you experienced headaches per week?
4. Since using your dose, have you experienced any of the following symptoms and, if so, how often per week did they occur?
   Trouble falling asleep
   Trouble staying asleep
   Trouble waking up
   Sleeping less than 7-8 hours per night
   Not feeling refreshed after a night of sleep
   Need naps during the day
5. Since using your dose, have you been experiencing feelings of depression, brain fog, mental confusion and/or memory problems at any time? If so, how often per week has this been occurring regarding each of these symptoms?
6. Since using your dose, have you been experiencing feelings of anxiety? If so, how many times per week has this occurred?
7. Since using your dose, have you had any of the following symptoms during any of the weeks you have been in the trial?

Pelvic or lower abdominal pain
A sensation or need to urinate frequently
Episodes of abdominal pain, abdominal cramps, constipation, diarrhea, heartburn, nausea or vomiting

8. Since using your dose, have you been experiencing any episodes of the following problems: abdominal pain, abdominal cramps, constipation, diarrhea, heartburn, nausea, or vomiting? If so, how many times per week has this occurred?
9. Since using your dose, have you experienced a lack of energy or fatigue? If so, how many times per week?
10. Since using your dose, have you felt chronically ill or "crappy" and, if so, how many times per week?
11. How many days per week did you take your dose?

RESULTS PRE-TRIAL VERSUS POST-TRIAL

Chronic Pain

Prior to engaging in the trial, 100% in all dose groups reported having pain and/or discomfort and/or muscle tenderness. After the trial, the following results were noted:

Dose 1 – 37 out of 39 still experienced chronic pain
Dose 2 – 39 out of 43 still experienced chronic pain
Dose 3 – 30 out of 44 still experienced chronic pain
Dose 4 – 5 out of 37 still experienced chronic pain (These 4 all reported using opiates, anti-depressants, analgesics, Pregabalin and/or Duloxetine).
Dose 5 – 40 out of 42 still experienced chronic pain

Fatigue

Prior to commencing the trial, all participants in all groups reported having episodes of fatigue. After the four week trial was completed, the results were as follows:

Dose 1 – 36 out of 39 still experienced fatigue Dose 2 – 37 out of 43 still experienced fatigue Dose 3 – 29 out of 44 still experienced fatigue

Dose 4 – 4 out of 37 continued to complain of fatigue (3 of 4 had not ceased taking their immune system, white blood cell modifying agents during the trial. These included Pregabalin and Duloxetine.

Dose 5 – 41 out of 42 still experienced fatigue or a lack of energy.

Headaches

Prior to commencing the trial, all participants were asked whether they were experiencing any level of headaches on a weekly basis. The results were as follows:

Dose 1 – 32 out of 39 prior to taking their dose had headaches at least once per week; post-trial 28 out of 39 continued to experience headaches at least once per week.

Dose 2 – 32 out of 43 complained of headaches at least once per week prior to the trial; after the trial was over 23 out of 43 continued to have headaches at least once a week.

Dose 3 – Pre-trial 36 out of 44 were having headaches at least weekly; post-trial 14 out of 44 were having headaches at least once per week.

Dose 4 – Pre-trial 27 out of 38 reported having headaches at least once per week, post-trial 6 out of 37 reported having headaches at least once per week (with all 6 of these not ceasing their use of immune-modulating, white blood cell modifying medications while on the trial).

Dose 5 – Pre-trial 26 out of 42 had headaches at least once per week; post-trial 26 out of 42 continued having headaches at least once per week.

Sleeplessness

Dose 1 – Pre-trial 21 out of 39 reported having sleep-related issues at least once per week; post-trial 20 out of 39 continued having sleep issues at least once per week.

Dose 2 – 17 out of 43 reported having sleep issues prior to the trial; post-trial 14 out of 43 continued having problems with sleep.

Dose 3 – 13 out of 44 had sleep issues pre-trial; post-trial 10 out of 44 had sleep issues at least once per week.

Dose 4 – Pre-trial 11 out of 38 reported having sleep issues at least once per week; post-trial 2 out of 38 reported having sleep issues at least once per week. These 2 reported using immune-modifying medications.

Dose 5 – Pre-trial 29 out of 42 reported having sleep issues at least once per week; post-trial the same 29 continued to have sleep issues at least once per week.

Depression, Brain Fog, Mental Confusion and/or Memory Problems

Dose 1 – 17 out of 39 reported having depression, brain fog, mental confusion and/or memory problems, with the predominant symptoms being brain fog and memory problems prior to the trial. Post-trial, 16 out of 39 still reported experiencing one or more of these symptoms.

Dose 2 – 15 out of 39 reported having depression prior to the trial. Post-trial, 13 reported feelings of depression, brain fog, mental confusion and/or memory problems.

Dose 3 – 20 out of 44 pre-trial reported having feelings of depression. Post-trial 19 out of 44 still had thoughts of depression, brain fog, mental confusion and/or memory problems.

Dose 4 – 15 out of 38 pre-trial reported having thoughts of depression or brain fog, mental confusion and/or memory problems. Post-trial 6 out of 38 had feelings of depression. Of these 6, all were either on opiates and/or Pregabalin or Duloxetine.

Dose 5 – 19 out of 42 reported having feelings of depression, brain fog, mental confusion and/or memory problems. Post-trial 17 out of 42 reported having feelings of depression.

Regarding feelings of Anxiety

Dose 1 – 11 out of 39 had feelings of anxiety. Post-trial 10 out of 39 had feelings of anxiety.

Dose 2 – 12 out of 43 reported having feelings of anxiety pre-trial. Post-trial 11 out of 43 reported having feelings of anxiety.

Dose 3 – 14 out of 44 pre-trial had feelings of anxiety. Post-trial 10 out of 44 had feelings of anxiety.

Dose 4 – 12 out of 38 had feelings of anxiety pre-trial. Post-trial 4 out of 38 had feelings of anxiety, all of whom had been using immune system, white blood cell modifying medications (Pregabalin and/or Duloxetine) during the trial.

Dose 5 – 13 out of 42 reported having feelings of anxiety pre-trial. Post-trial 10 out of 42 reported having feelings of anxiety.

Genitourinary

Prior to engaging in the trial, 3 out of the dose groups reported having chronic pelvic area pain with frequent urination. They had been diagnosed to have interstitial cystitis. Of those 3, none received the Dose 4 of M. smegmatis. One had received Dose 2 and reported no change in their symptoms. Two received Dose 3 and one of them noticed a "slight" lessening of their symptoms.

Gastrointestinal symptoms which included episodes of abdominal pain, abdominal cramps, constipation, heartburn, nausea, vomiting or diarrhea.

Dose 1 – None of the 39 reported having any of the gastrointestinal symptoms

Dose 2 – 14 out of 43 reported having some gastrointestinal symptoms with just 1 feeling improved.

Dose 3 – 12 out of the 44 initially had gastrointestinal symptoms with 10 reporting improvement post-trial.

Dose 4 – 12 out of 38 reported having gastrointestinal symptoms pre-trial. All 12 noted an improvement post-trial.

Dose 5 – 10 out of 42 had gastrointestinal symptoms pre-trial. Post-trial 2 reported feeling less gastrointestinal symptoms.

Lack of energy. Prior to commencing the trial, all participants in all groups reported having a lack of energy. After the four week trial was completed, the results were as follows:

Dose 1 – 36 out of 39 still experienced a lack of energy. Dose 2 – 37 out of 43 still experienced a lack of energy. Dose 3 – 29 out of 44 still experienced a lack of energy.

Dose 4 – 4 out of 37 continued to complain of a lack of energy. (All 4 had been taking one or more of the following: Pregabalin, Duloxetine, opiates.)

Dose 5 – 41 out of 42 still experienced a lack of energy.

Generally feeling poor/"Crappy"

Dose 1 – 29 out of 39 pre-trial reported feeling chronically ill or "crappy." Post-trial 27 out of 39 continued to have these symptoms.

Dose 2 – 37 out of 43 reported having feelings of chronic illness/"crapiness." Post-trial 25 out of 43 continued to have these symptoms.

Dose 3 – 34 out of 44 reported having feelings of chronic illness/"crapiness." Post-trial 30 out of 44 continued to have these symptoms.

Dose 4 – 36 out of 38 reported feeling chronically ill with "crapiness" pre-trial. Post-trial 6 out of 38 continued to remain symptomatic and all 6 were taking opiates, narcotics, psychotropic medications and/or immune system, white blood cell modifying agents of Pregabalin and/or Duloxetine.

Dose 5 – 30 out of 42 pre-trial reported having feelings of chronic illness/ "crapiness." Post-trial 22 out of 42 reported still being symptomatic.

FDA Approved Fibromyalgia Medications

The US FDA has approved three medications for the treatment of fibromyalgia. These include Pregabalin (Lyrica), Duloxetine (Cymbalta) and Milnacipran (Savella). Pregabalin is an anticonvulsant. Duloxetine and Milnacipran are anti-depressants. All three carry FDA "Black Box Warnings" in reference for their risks for leading to mental depression, suicidal ideation and suicide. All three are also known to be immune modifying agents in that they can cause potentially serious decreases in white blood cells. This is pertinent information in light of the fact that the research published by Behm, et al.,2 documented that patients with fibromyalgia suffer with abnormal white blood cell pathways. It therefore was confirmed that by using M. smegmatis, which can reverse the protein deficient functioning of the white blood cell of peripheral blood mononuclear cells, the actions of the latter three medications do, indeed, promote the continued pathologic features that hallmark fibromyalgia. Hence, the use of the latter three medications by participants of the study revealed additional documentation of their adverse consequences in reference to white blood cell functioning wherein they will mask fibromyalgia symptoms while actually promoting the basis for those symptoms. Additionally, in the research cited for their FDA approval, the results were based upon subjective patterns and not on actual pathologic-immune system-white blood cell based science.

DISCUSSION

Fibromyalgia is estimated to affect up to 6% of the population, whether in the United States or on a worldwide basis. For a variety of reasons its definition has been pummeled by innuendoes, suppositions and misrepresentations. In particular, it has primarily suffered from the implication that it is not an actual disease with specific and definable pathology. However, with the discovery and documentation

of unique immune system deficiencies and an underlying confirmation of related unique DNA genomic signatures, it has been proven to meet all of the definitions of a pathologic illness with unequivocal objective criteria. Based upon that criteria, we sought a method to reduce and/or eliminate the manifestations of this disease both subjectively and based upon proven objective successes.

We therefore recruited a large group of individuals who composed a control group and those documented to have the inherent immune system deficiencies which define fibromyalgia. We then analyzed a potential therapeutic agent based upon the documented effects of the reversal in an in-vitro setting regarding these immune system deficiencies which were associated with a particular Mycobacterium; Mycobacterium smegmatis.

Patients were segregated via double-blind/placebo methodology. They were monitored for a period of 30 days and asked to compare their fibromyalgia-related symptoms pre and post the use of a Mycobacterium smegmatis capsule. The results proved dramatic even when analyzed in the context of the continuing use of particular compounds which were known to be able to thwart the actions of Mycobacterium smegmatis. Nevertheless, an effective dose of this non-pathogenic bacteria was identified. Except for those individuals who were using Mycobacterial dysbiotic substances, the efficacy was 100% at a dose of 250 mg of Mycobacterium smegmatis per day. This was based upon analyzing each patient for classic groups of fibromyalgia-related symptoms. A statistically relevant improvement in those symptoms was documented at the 250 mg dose of Mycobacterium smegmatis in all of those 9 symptoms. This included patient responsess relative to their affliction of chronic pain(pain which existed for 3 or more months).

No untoward effects from Mycobacterium smegmatis were documented to have occurred.

The value of this study was not merely to reiterate an objective way to diagnose fibromyalgia. It also led to evidence of an effective therapeutic pathway capable of lessening and/or eliminating the majority of symptoms associated with the disease of fibromyalgia, including but not limited to chronic pain.

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