

Survey of 267 Patients Using Low Dose Naltrexone for Multiple Sclerosis

Summary

Multiple sclerosis (MS) is an autoimmune disorder in which neuronal damage accumulates over time, leading to paralysis and multiple physical dysfunctions. MS is a leading cause of disability in Western nations among young adults, but scientists don't yet know what causes it.

Current treatments for MS consist of immunomodulatory drugs administered by self-injection, including Avonex, Betaseron, Copaxone and Rebif. For people with more advanced forms of the disease, chemotherapy is used to kill or suppress the over-active immune system. These medications aim to halt disease progression, but only work for some patients. In addition, these drugs have unpleasant side effects, and are expensive, around \$1,000 per mo.

There is growing world-wide interest among people with multiple sclerosis in the use of Low Dose Naltrexone (LDN). Part of the attraction is the low cost (around \$15 per mo). The other is compelling anecdotal reports, both from patients and clinical practitioners, citing relief from symptoms, and a halt to attacks and progression. One such practitioner is Dr. Bernard Bihari, a Harvard trainer neurologist practicing in New York City. Over the last 20 years, he has prescribed LDN to over 1,000 patients, for a wide range of ailments stemming from immune system impairment, including MS. As of May 2004, among his 400 MS patients, he states only two have shown evidence of new symptoms or disease activity since starting LDN.

The FDA approved use of Naltrexone (at doses of 50 to 150mg a day) is for treatment of those addicted to opiates, such as heroin. It does this by blocking opiate receptors in the brain, thus making the drugs less pleasurable. There have been several hundred trials of Naltrexone in various forms of addiction. The dosage level employed in LDN therapy (3 to 4.5 mg) is much lower than that already investigated in these earlier human safety trials. This precludes human safety trials as a first step in clinical trials of LDN for immunity related disorders, which means lower investigative costs and shorter time to determination of LDN's effectiveness and method of action.

So far there is one ongoing clinical trial of LDN against autoimmune disease. Dr. Jill Smith at Penn State College of Medicine is currently enrolling to test effectiveness of LDN for symptom relief in Crohn's Disease.

In order to stimulate interest among other academic researchers in LDN trials for MS, an online patient tracking system has been devised. The subjects were self-selected, after seeing an invitation to participate in the survey posted at various online MS discussion forums. While not a scientific or controlled study, the survey form applies consistency across patient self-reports, allowing statistical analysis of medical facts such as relapses and symptoms. The most significant finding is an extremely low relapse rate of 0.226, or 1 in 5 years. For comparison, one study reports the following relapse rates for other MS therapies: Copaxone - 0.49; Betaseron - 0.55; Avonex - 0.81; Untreated - 1.02¹. The more subjective questions, such as symptom relief, are also surprisingly positive. The symptom relief rating ranges from 57-82% positive, by type of MS. These findings are put forth as a compelling indicator that Low Dose Naltrexone deserves clinical research attention, for the treatment of multiple sclerosis.

¹ A prospective, open-label treatment trial to compare the effect of IFNbeta-1a (Avonex), IFNbeta-1b (Betaseron), and glatiramer acetate (Copaxone) on the relapse rate in relapsing--remitting multiple sclerosis: results after 18 months of therapy. PMID: [11795454](#)

Naltrexone is an FDA-approved drug. LDN is an off-label use of naltrexone in a low dosage. It does requires a prescription from a doctor.

Overall Analysis of 267 Responses to the LDN Survey: Duration of Treatment and Relapse Rate as of 7/12/2004

Months of LDN	Subjects	Yrs Of LDN	Yrs Avg	Relapses On LDN	Relapse Rate / Yr	Years Diagnosed
0-3 Mo	133 50%	17.82	0.13	3	0.168	1150.35
4-6 Mo	45 17%	18.50	0.41	7	0.378	467.05
7-11 Mo	25 9%	17.25	0.69	3	0.174	227.50
> 12 Mo	64 24%	131.92	2.06	29	0.220	806.25
Total	267	185.49	0.69	42	0.226	2651.15

Breakdown by Type of MS: Duration of LDN Treatment and Relapse Rate

Months of LDN	Subjects	Yrs Of LDN	Relapses On LDN	Relapse Rate / Yr	Years Diagnosed
0-3 Mo	15 44%	2.61	1	0.383	139.50
4-6 Mo	4 12%	1.58	0	0.000	63.00
7-11 Mo	7 21%	4.92	0	0.000	112.50
> 12 Mo	8 24%	18.58	1	0.054	76.00
Total (PPMS)	34	27.69	2	0.072	391.00
0-3 Mo	5 42%	0.58	0	0.000	44.00
4-6 Mo	2 17%	0.75	0	0.000	13.00
7-11 Mo	1 8%	0.67	1	1.500	9.00
> 12 Mo	4 33%	11.00	2	0.182	64.00
Total (PRMS)	12	13.00	3	0.231	130.00
0-3 Mo	63 54%	7.60	1	0.132	391.85
4-6 Mo	17 15%	6.71	4	0.596	120.05
7-11 Mo	11 9%	7.58	1	0.132	65.50
> 12 Mo	25 22%	46.25	12	0.259	228.75
Total (RRMS)	116	68.15	18	0.264	806.15
0-3 Mo	50 48%	7.03	1	0.142	575.00
4-6 Mo	22 21%	9.46	3	0.317	271.00
7-11 Mo	6 6%	4.08	1	0.245	40.50
> 12 Mo	27 26%	56.08	14	0.250	437.50
Total (SPMS)	105	76.65	19	0.248	1324.00
Total	267	185.49	42	0.226	2651.15

Primary Progressive (PPMS)

Female 17
Male 17

Have Symptoms Improved After LDN?

Symptoms have improved	18	53%
Symptoms have stayed the same	14	41%
Symptoms are worse	2	6%
Total (PPMS)	34	

What about disease progression?

I think progression has stopped	17	50%
I think progression has worsened	4	12%
Too soon to tell	13	38%
Total (PPMS)	34	

Is LDN working for you?

Yes, it is helping and will continue	26	76%
Not sure at this time	5	15%
No, I don't think it is helping	3	9%
Total (PPMS)	34	

	Months on LDN	Relapses since starting LDN	.072 / yr	Mg Dosage LDN	# Years Diagnosed
Sum	332.30	2.00			391.00
Avg	9.77	0.06		3.88	11.50
Min	0.30	0.00		3.00	1.00
Max	43.00	1.00		6.00	27.00

Primary Progressive (PPMS) Total: 34 Percent of total responses 12.73%

Progressive Relapsing (PRMS)

Female 9
Male 3

Have Symptoms Improved After LDN?

Symptoms have improved	9	75%
Symptoms have stayed the same	2	17%
Symptoms are worse	1	8%
Total (PRMS)	12	

What about disease progression?

I think progression has stopped	7	58%
I think progression has worsened	1	8%
Too soon to tell	4	33%
Total (PRMS)	12	

Is LDN working for you?

Yes, it is helping and will continue	10	83%
Not sure at this time	1	8%
No, I don't think it is helping	1	8%
Total (PRMS)	12	

	Months on LDN	Relapses since starting LDN	.231 / yr	Mg Dosage LDN	# Years Diagnosed
Sum	156.00	3.00			130.00
Avg	13.00	0.25		4.33	10.83
Min	1.00	0.00		3.00	1.00
Max	48.00	1.00		4.50	21.00

Progressive Relapsing(PRMS) Total: 12 Percent of total responses 4.49%

Breakdown by Type of MS: LDN Patient's Subjective Symptom Observations

as of 7/12/2004

Relapsing/Remitting (RRMS)

Female 75
Male 41

Have Symptoms Improved After LDN?

Symptoms have improved	95	82%
Symptoms have stayed the same	17	15%
Symptoms are worse	4	3%
Total (RRMS)	116	

What about disease progression?

I think progression has stopped	40	34%
I think progression has worsened	4	3%
Too soon to tell	72	62%
Total (RRMS)	116	

Is LDN working for you?

Yes, it is helping and will continue	87	75%
Not sure at this time	27	23%
No, I don't think it is helping	2	2%
Total (RRMS)	116	

	Months on LDN	Relapses since starting LDN	.264 / yr	Mg Dosage LDN	# Years Diagnosed
Sum	817.75	18.00			806.15
Avg	7.05	0.16		4.05	6.95
Min	0.00	0.00		2.00	0.25
Max	48.00	5.00		30.00	28.00

Relapsing/Remitting (RRMS) Total: 116 Percent of total responses 43.45%

Secondary Progressive (SPMS)

Female 73
Male 32

Have Symptoms Improved After LDN?

Symptoms have improved	60	57%
Symptoms have stayed the same	34	32%
Symptoms are worse	11	10%
Total (SPMS)	105	

What about disease progression?

I think progression has stopped	45	43%
I think progression has worsened	11	10%
Too soon to tell	49	47%
Total (SPMS)	105	

Is LDN working for you?

Yes, it is helping and will continue	73	70%
Not sure at this time	24	23%
No, I don't think it is helping	8	8%
Total (SPMS)	105	

	Months on LDN	Relapses since starting LDN	.248 / yr	Mg Dosage LDN	# Years Diagnosed
Sum	919.80	19.00			1324.00
Avg	8.76	0.18		3.73	12.61
Min	0.00	0.00		1.50	1.00
Max	54.00	4.00		6.00	35.00

Secondary Progressive (SPMS) Total: 105 Percent of total responses 39.33%

Grand Total	Months on LDN	Relapses since starting	Mg Dosage LDN	# Years Diagnosed
	2225.85	42.00		2651.15

Notes: 28 individual users out of 267 reported a total of 42 relapses.