

A trial of prednisone and acetaminophen versus acetaminophen alone in minimizing flu-like symptoms from pegylated interferon beta-1a

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Introduction:

Multiple Sclerosis (MS) is a chronic neurological disease characterized by demyelination of the brain and spine. Currently, there are several treatments designed to decrease the frequency of attacks and delay disease progression. One of these treatments, a subcutaneous disease-modifying therapy called pegylated interferon beta-1a (Plegridy), has shown the potential to decrease relapse rates by approximately 30% and last longer in the body. There are, however, some common side effects of this interferon therapy such as flu-like symptoms (FLS) and injection site reactions (ISR), which can cause patients to discontinue further treatment.

Objective:

Because Plegridy lasts longer in the body and has more convenient dosing for patients (once every two weeks), researchers in this study decided to investigate whether taking acetaminophen alone or in combination with prednisone before the injection would help decrease or prevent the occurrence of flu-like symptoms and injection site reactions in patients taking Plegridy.

Study Design:

- N=50 patient interventional series.
- Two ARMs: current and new Plegridy users, however, new were required to be titrated with Plegridy before taking full 125 microgram dose.
- Six full-dose Plegridy injections; 12-16 week study duration.
- All participants were instructed to take two 325mg Tylenol (acetaminophen) tablets prior to each Plegridy injection; prior to the second through sixth full-dose of Plegridy, patients took one 20mg prednisone tablet in addition to the Tylenol.
- Patients reported their flu-like symptoms on FLS questionnaires, while ISR's were addressed during weekly follow-up calls by the investigators.

Preliminary Results:

Results reported include data received thus far (N=10), as this study is still enrolling patients. So far a total of 8 patients experienced an ISR or FLS (4 existing and 4 new users). Overall FLS significantly less severe in current users than new users ($p = .001$).

	New or existing Plegridy user				APAP (Tylenol)	
	Existing user		New user		APAP only	
	Median	Mean	Median	Mean	Median	Mean
Cumulative FLS score (0-108) within 48 hours	3.0	3.7	15.5	15.4	14.0	11.8
ISR area (cm ²)	16.00	15.08	6.00	14.86	9.00	17.43

Areas of Difficulty:

- Prolonged compliance
- External patient factors may affect data
- Multiple variables in analyses



Areas of Improvement:

- Have both ARMs take full dose Plegridy injection without Tylenol or Prednisone
- Include lifestyle and demographic questionnaires in data collection

Key Points:

- FLS less severe in existing Plegridy users
- No significant difference yet established from Tylenol and prednisone in relieving side effects