

## Information for patients from JNNP

### Common MS drug linked to longer life

A new study sheds light on the long-term effects of a drug taken by many people with multiple sclerosis (MS). In the longest-ever follow-up study of interferon beta-1b, researchers found that people who took the drug for two or more years were less likely to die during 16 years of follow-up than those who took an inactive treatment. However, there was no difference between the groups in how likely their disease was to worsen and lead to disability.

#### What do we know already?

Many people with MS take disease-modifying drugs (DMDs) to prevent flare-ups of symptoms. One of the most widely used is interferon beta-1b (brand names Betaferon/Betaseron). It's often prescribed to people who have relapsing-remitting MS. This means they get bouts of symptoms (relapses) that eventually go away (remit).

Interferon beta-1b was an experimental treatment in the early 1990s when researchers embarked on a two-year study of 372 people with relapsing-remitting MS. Participants were randomly assigned to have injections of an inactive (placebo) treatment every two days, or injections of interferon beta-1b, at a dose of either 50 micrograms (mcg) or 250 mcg. Participants continued having these treatments for at least two years, and some carried on for five years or longer.

This pivotal study found that people taking interferon beta-1b were more likely to be relapse-free after two years, and their relapses were less frequent and severe, particularly if they took the higher dose. The drug was soon approved for treating relapsing-remitting MS and became widely used.

However, questions have remained about the drug's long-term effects, both in terms of possible harms and benefits. To learn more, researchers have now revisited the original study to follow up with participants. One recent study focused on the drug's safety and found no important long-term safety concerns. Now researchers have done a study focusing on the possible long-term benefits of taking the drug.

#### What does the new study say?

The researchers followed up with 328 of the study's original 372 participants. They found no differences between the placebo and interferon beta-1b groups in their level of disability 16 years after the start of the study. However, 18.3 percent of those in the placebo group had died, compared with only 5.4

percent in the high-dose interferon beta-1b group and 8.3 percent in the lower-dose group.

The researchers weren't able to confirm the cause of death for most of the participants, so they can't say whether the deaths were related to MS or other factors.

The researchers also looked at people's use of interferon beta-1b after the original study had ended. They found that people who used the drug more than 13 years in total were slightly less likely to be disabled or have developed a more severe type of MS (secondary progressive MS), compared with those who used the drug less than 2 years. However, the differences between the groups were small enough that they could have been down to chance.

### **How reliable are the findings?**

A follow-up study like this is useful for spotting possible trends and helping to direct future research. The study accomplishes this, by showing that interferon beta-1b may play a role in helping people with MS live longer.

However, it can't tell us for certain whether interferon beta-1b actually added years to people's lives. This is because the follow-up study didn't adhere to the strict standards of the original study, which closely controlled what treatments people had. After the original study ended, the participants' treatment was managed by their individual doctors, not the researchers. And there wasn't a placebo group for comparison. All this means that researchers can't be sure whether the long-term benefits they noted in the interferon beta-1b groups were because of the drug, some other treatment, or possibly chance.

Also, it's important to note that only 35 people died during the follow-up period, which is a small number for basing any conclusions on whether the drug might help people live longer.

### **Where does the new study come from?**

The study was done by researchers in the UK, US, Canada and Germany, and was funded by Bayer HealthCare Pharmaceuticals, a manufacturer of interferon beta-1b.

### **What does this mean for me?**

If you are taking interferon beta-1b for relapsing-remitting MS, this study suggests that the drug might help you live longer. However, this benefit is still only theoretical and we need more research to confirm it.

### **What should I do now?**

There's nothing you need to do based on this research. However, if you have relapsing-remitting MS and have questions about interferon beta-1b treatment, talk to your doctor. There are also other disease-modifying drugs for MS, including glatiramer acetate and natalizumab. You and your doctor can weigh up the pros and cons of these medicines and decide on the treatment approach that's best for you.

**You can access the full article for free online**

Ebers GC, Traboulsee A, Li D, et al. Analysis of clinical outcomes according to original treatment groups 16 years after the pivotal IFNB-1b trial. *Journal of Neurology, Neurosurgery, and Psychiatry*. 2010; 81: 907-912. <http://jnnp.bmj.com/content/81/8/907.full>

This summary was prepared by the staff of Best Health, BMJ Group's patient information service. This information does not replace medical advice. If you have a medical problem please see your doctor.

