Evaluation of the effect of seasonal weather variations on adherence and effectiveness of subcutaneous interferon β-1a administered by RebiSmart® in patients with relapsing multiple sclerosis: final results of the 1-year, observational GEPAT-SMART study

Deftereos SN. (Main Author),[1] Koutlas E.,[2] Koutsouraki E.,[3] Kyritsis A.,[4] Papathanassopoulos P,[5] Fakas N.,[6] Tsimourtou V.,[7] Vlaikidis N,[8] Tavernarakis A,[9] Voumvourakis K,[10] Arvanitis M,[11] Sakellariou D.[1], Filippo DeLorenzo[1]

[1] Merck Hellas, [2] Papageorgiou Hospital of Thessaloniki, [3] University of Thessaloniki, [4] University of Ioannina, [5] University of Patras, [6] 401 Army Hospital of Athens, [7] University of Thessaly, [8] University of Thessaloniki, [9] Evangelismos Hospital, [10] University of Athens, [11] Private Practice

Short Title: Effect of weather variations on scIFN-β1a adherence

Abstract

Background

Flu-like syndrome and injection site reactions have been associated with poor adherence to the interferons. However, little is known about whether tolerability and adherence to treatment can be influenced by weather.

Objective

To assess adherence to subcutaneous interferon beta-1a (scIFNβ-1a) treatment in relapsing-remitting multiple sclerosis (RRMS) patients using the RebiSmart® electronic autoinjector according to seasons at one year.

Methods

This is a multicentric, prospective observational study in Greece. Sixty four RRMS adult patients with EDSS < 6 receiving scIFNβ-1a/RebiSmart® for ≤ 6 weeks were enrolled in the study. From these, 47 completed all study visits (Per Protocol Set - PPS). The primary endpoint was adherence over 12 months, defined as 100x number of injections actually administered divided

by the expected number of injections over the defined time period (month, season, year). Secondary endpoints included number of relapses,disability and adverse events. This manuscript was development according to the STROBE guideline for reporting observational studies. Descriptive statistics were calculated for all study variables. Seasonal and monthly variance of the adherence level was analyzed by One Way Analysis of Variance (ANOVA). Pre- and post-treatment relapse rate was compared by the Wilcoxon signed-rank test. Pearson's r was used to study correlation between variables.

Results

Mean annual adherence to scIFNβ-1a/RebiSmart® was 97.93%±5.704 with no significant monthly, seasonal or geographical variations. Mean relapse rates in the pre- and post- treatment were 1.1±0.47 and 0.2±0.54 respectively ($p < 0.001$, PPS). Eighteen patients (38%) showed improvement, nineteen stabilized (40%) and ten worsened (22%) in terms of disability progression at 3 months. EDSS did not correlate with pre- (r=0.024, p=0.87) or post-treatment relapses (r=0.022, p=0.88).

Conclusion

Our study demonstrates that adherence to SC IFN with RebiSmart® was high but independent of seasonal changes. Efficacy on relapses was consistent with published studies.