NATALIZUMAB EVERY 6 WEEKS VERSUS STANDARD DOSE: EVALUATION OF EFFECTIVENESS. PRELIMINARY STUDY

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CP-101
N-07

Background

Natalizumab is a selective adhesion-molecule-inhibitor and binds to the α4-subunit of human integrins.
Natalizumab 300 mg is administered by intravenous infusion once every 4 weeks (standard dose).

Purpose

To evaluate and compare the effectiveness of natalizumab administered every six weeks versus the standard dose in patients diagnosed with relapsing-remitting multiple sclerosis (RRMS).

Material and methods

Retrospective and observational study of patients diagnosed with RRMS treated with Natalizumab between January 2013 and June 2016. Inclusion criteria: Patients≥18 years old, optimal response to natalizumab and <65 kg. Variables collected: demographics (age and sex); clinical: mental state/mood (MS/M), Vision (V), language (L), Hearing/vertigo (H/V), Swallow (S), Cerebellum (C), cranial (PC), cervical mobility (CM) Motor System (MS), Sensitive System (SS), Balance (BA), Romberg (R), March (M), sphincters/sexual function (SF), buds (B) and presence of anti-John Cunningham virus (JCV) antibodies at 0, 3 and 6 months of dosing change. Statistical analysis was performed using the Epidat 3.1 program.

Results

30 patients were included (23% male) with a mean age of 36.1±12.9 years. The following table shows the number of patients who developed alterations for each of the variables studied.

Variables	0m	3m	p3m	6m	p6m
MS/M	10	10	1	9	0.8443
V	11	11	1	12	0.8621
L	10	9	0.8443	8	0.6841
H/V	9	8	0.8332	7	0.6614
S	2	2	1	2	1
C	7	6	0.8040	7	1
PC	3	3	1	3	1
CM	2	1	0.5706	2	1
MS	15	14	0.8817	14	0.8817
SS	20	19	0.9036	17	0.7059
BA	17	18	0.8960	14	0.6694
R	9	8	0.8332	10	0.8443
M	17	17	1	18	0.8960
SF	10	12	0.7205	12	0.7205
B	NO	NO	1	NO	1
JCV	1 +	1 +	1	1 +	1

Table 1: 0 (0m), 3 (3m) and 6 (6m) months dosing change.

Conclusion

No statistically significant differences were observed when comparing the results obtained for each of the items studied at 0, 3 and 6 months after the change of dosage, so we could conclude, preliminarily, that both dosing regimens appear to be equally effective in this group of patients.