

Improvement of Disability Level with Enkorten Therapy in Patients Suffering from Relapsing-Remitting Multiple Sclerosis (RRMS)



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Introduction

Enkorten® is combination of two neuropeptides that participate in modulation of immunological processes:

- metenkefalin (acetate).....5 mg
- tridecactide (acetate)..... 1 mg

Tridecactide main mode of action is prevention of NF- κ B activation which results in down regulation of the production of proinflammatory and immunomodulating cytokines. Metenkefalin exerts its action through binding to the δ opioid receptors that are located on the neuronal cells and the cells of the immune system.

The effect of both peptides includes analgesia, antipyretic, antioxidant and anti-inflammatory effects without side effects related to steroid and non-steroid anti-inflammatory drugs^{1,2}.

Objectives

Objectives of the study was to evaluate the efficacy and safety of Enkorten® in the treatment of relapse-remitting (RR) MS.

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| 1) Efficacy | 2) Safety |
| Diameter, volume and number of MRI T1 and T2 lesions | blood and urine analysis |
| EDSS score | adverse events |
| Time to first relapse | |
| Number and duration of relapses | |
| Relapse-free patients | |

The study was conducted at the Clinic of Neurology, Clinical Center, University of Sarajevo, Bosnia and Herzegovina. The study was a randomised, open and comparative study lasting for 6 months.

Patients

- Suffering from RR-MS
 - 40 patients received Enkorten®
 - 40 patients in control group
- EDSS (Expanded Disability Status Score) 0 do 5.5

Table 1. Demographic details and clinical parameters at baseline in patients suffering from RR-MS

	Enkorten®	Control
Age (yrs)	40.5	39.1
F:M	33:7	28:12
BMI	24.7	23.2
EDSS	2.9	2.5
Time since symptom onset (yrs)	10.7	7.4
Time since diagnosis (yrs)	5.7	2.7

Enkorten® reduced disability level

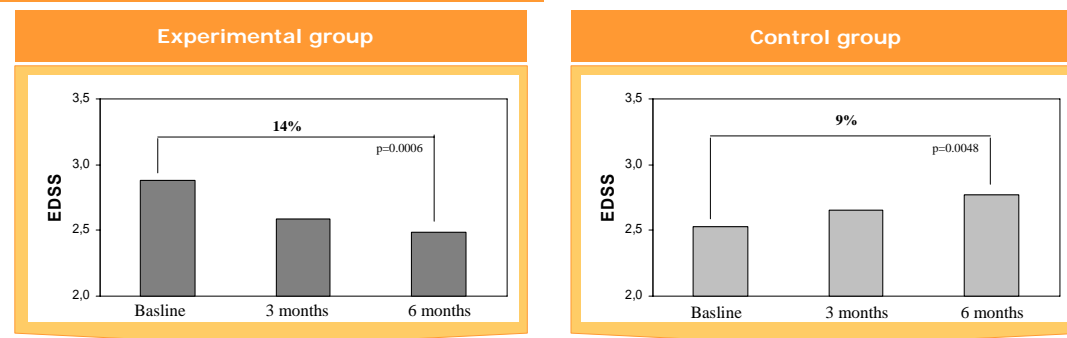


Figure 1. EDSS in RRMS patients in experimental and control group at baseline and after 3 and 6 months

Table 2. Number of patients (%) who showed improvements, worsening or no change in EDSS in control and experimental group at the end of the study (6 months) compared to EDSS at the beginning of the study

EDSS score change at 6 months from baseline EDSS score	Control (n=39)*	Experimental (n=39)*
Unchanged	16 (41.0%)	10 (25.6%)
Improvement	6 (15.4%)	26 (66.7%)
0.5	3	17
1.0	2	7
1.5	1	2
2.0	0	0
2.5	0	0
Worse	17 (43.6%)	3 (7.7%)
0.5	10	1
1.0	4	2
1.5	1	0
2.0	2	0
2.5	0	0

Conclusions

Enkorten® demonstrated statistically significant efficacy in modification of natural course of disease through reduction of disability level as measured by EDSS scale, reduction in size of T1 and size and volume of T2 MRI lesions and reduced relapse rate during the 6 months of Enkorten® application.

EDSS score significantly increased in the patients within the control group ($p=0.048$) whereas significant improvement in the EDSS score was noted within the group of patients taking Enkorten during the 6 months of the study ($p=0.0006$).

Enkorten® was used as a treatment for relapses during the study in the patients from the experimental group. Enkorten® accomplished 100% substitution of corticosteroid pulse therapy in all patients requiring treatment.

Enkorten® has shown remarkable safety profile with no severe adverse events being reported during 6 months of Enkorten® application.

Literature

- 1) Konjevoda et al., *J Physiol – Paris*, 95, 2001, 277-281
- 2) Konjevoda et al., *Period Biol*, 106, 2004, 355-359