

Effects of Enkorten Therapy on Relapse Related Parameters 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

The mechanism of action of Enkorten® in the treatment of multiple sclerosis (MS) consists of immunomodulatory effects of which it is important to point the ability of Enkorten® to modify cytokine production that in turn modulate the response of immune system and the release of new immune mediators.

Objectives

Objectives of the study were to determine influence of Enkorten® in patients with relapsing-remitting (RR) form of MS on relapse parameters:

- time to first relapse,
- duration of relapses during the study,
- number of relapses during the study,
- number of relapse free patients.

The 6 months study was carried out at the Neurology Clinic, Clinical Center, University of Sarajevo, Bosnia and Herzegovina as a randomised, parallel, prospective and comparative study.

Study Design

Table 1. Study design of a randomised, parallel group (experimental-Enkorten and control), prospective study.

	Baseline		Study	
	-1		12	24
Week			12	24
Day	-7	-6 to -1	84 (± 4)	168 (± 4)
Signing of informed consent form and contraceptive use form (Neurologist)	x			
Complete neurological examination with confirmation of RRMS diagnosis (Neurologist)	x		x	x
EDSS (Neurologist)	x		x	x
MRI (Radiologist)		x	x	x
Examination by specialist of internal medicine		x	x	x
Laboratory analysis of urine and blood		x	x	x
Adverse events reporting			x	x

Patients

Table 2. 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 (Body mass index)	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

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

Results

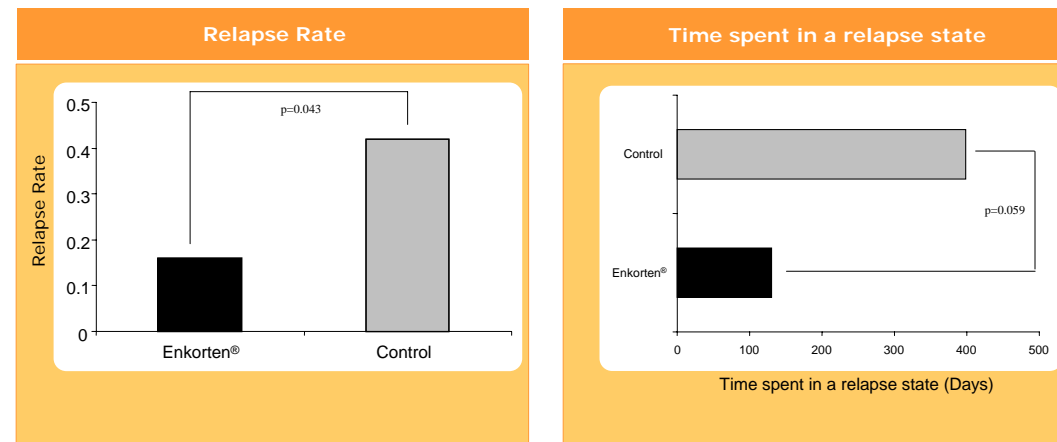


Figure 1. Relapse rate (mean) during the study and time spent in a relapse state for control and Enkorten® group.

- Statistical trend was seen in the time to first relapse between the experimental (173 ± 6 days, mean \pm SEM) and control (152 ± 10 days) ($p=0.0518$, Log-rank test).
- Mean number of days spent in a relapse was lower in the experimental (3.3 ± 1.4 days) compared to control (10.0 ± 1.4 days) ($p=0.059$, Man Whitney test).
- In the experimental group 34 out of 40 patients remained relapse free while 26 out of 40 patients in the control group remained relapse free ($p=0.0518$, Log-rank test).
- There was 16 relapses in the control group compared to 6 relapses in the experimental group during the six months of the study ($p=0.058$, Man Whitney test)

Conclusions

Number of relapses: A reduction of 63% in number of relapses was noted in the experimental group compared to control group during the study.

Duration of relapse: In addition, duration of relapse state during the study was reduced by 67% in experimental compared to control group.

Time to first relapse: Cumulative probability of time to first relapse was longer in patients taking Enkorten (experimental group) compared to patients who were free from medication for MS (control group).

Number of relapse-free patient: 85% of patients in experimental and 67% in the control group remained relapse free throughout the study period of 6 months.

Enkorten® was used as a treatment for relapses during the study in the patients from the experimental group. Enkorten® has demonstrated its ability as a treatment that can be successfully used as a substitution for corticosteroid pulse therapy during the relapses with reduction in duration of these relapses and absence of adverse events that usually accompany corticosteroids. Only one patient that had relapse of the MS in the experimental group opted for corticosteroids during the relapse during 6 months of the study.

Enkorten® has shown remarkable safety profile with no severe adverse events being reported during 1 year of Enkorten® application.

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