

# Cinnoomer<sup>®</sup> 40

Glatiramer Acetate  
Physioject<sup>™</sup>



Simplicity  
Reliability  
Safety



شرکت سیناژن  
CinnaGen

# CinnoMer<sup>®</sup> 40

Glatiramer Acetate



CinnoMer 40 mg

Better fitness into patients life

**MS control with 3-times-a-week of GLATIRAMER ACETATE 40 mg**

### STUDY DESIGN<sup>1</sup>

3-times-a-week  
CinnoMer<sup>®</sup> (glatiramer acetate injection) 40 mg

### WHO

- 1404 people with RRMS
- 943 taking glatiramer acetate 40 mg
  - 461 taking placebo

### WHAT

A 12-month, double-blind, placebo-controlled, multinational study

### WHY

- The primary study objective was to measure the total number of confirmed relapses in people with RRMS over a 12-month period
- The secondary study objective was to measure the reduction in the cumulative number of T1 and T2 lesions—types of brain lesions as assessed by MRI at 6 and 12 months

### SAMPLE SCHEDULE: 3-times-a-week DOSE<sup>1</sup>

SAT.	SUN.	MON.	TUES.	WED.	THUR.	FRI.
		1		2		3

injection at least 48 hours apart

## GLATIRAMER ACETATE 40 mg

Glatiramer has promising impact on MRI in RRMS

fewer relapses compared with placebo<sup>1</sup>

Primary results

34%

Relapses, also called flare-ups or attacks, can cause new symptoms to occur and make old symptoms worse

3-times-a-week GLATIRAMER ACETATE 40 mg reduced the number of relapses by 34% compared with placebo (an inactive substance)

## GLATIRAMER ACETATE 40 mg

improvement of MRI lesions

Primary results

34%

T2 lesions show areas where the brain tissue has been damaged

reduction in the total number of new and enlarging T2 lesions<sup>1</sup>

Primary results

45%

T1-enhancing lesions, also known as Gadolinium enhancing T1 lesions, show areas where brain tissue is currently being attacked.

reduction in the total number of enhancing lesions on T1-weighted images<sup>1</sup>

3-times-a-week GLATIRAMER ACETATE 40 mg showed a significant cumulative reduction in the underlying disease activity as measured by brain lesions on magnetic resonance imaging (MRI) at 6 and 12 months compared to placebo.

**Reference:**

Glatiramer acetate prescribing information, UptoDate 2015



# Cinnomer<sup>®</sup> 40

## Glatiramer Acetate

### Autoinjector



Simplicity / Reliability / Safety

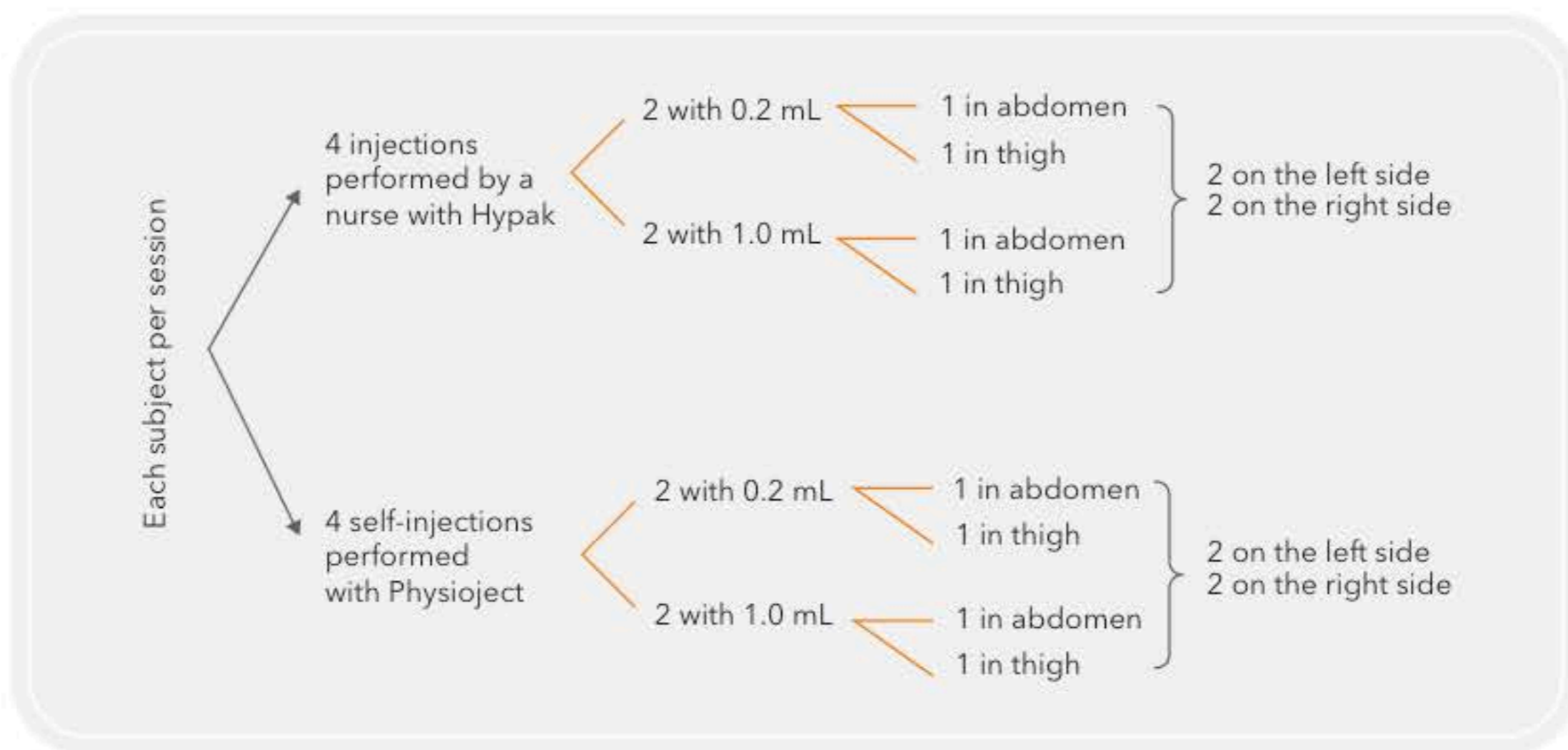
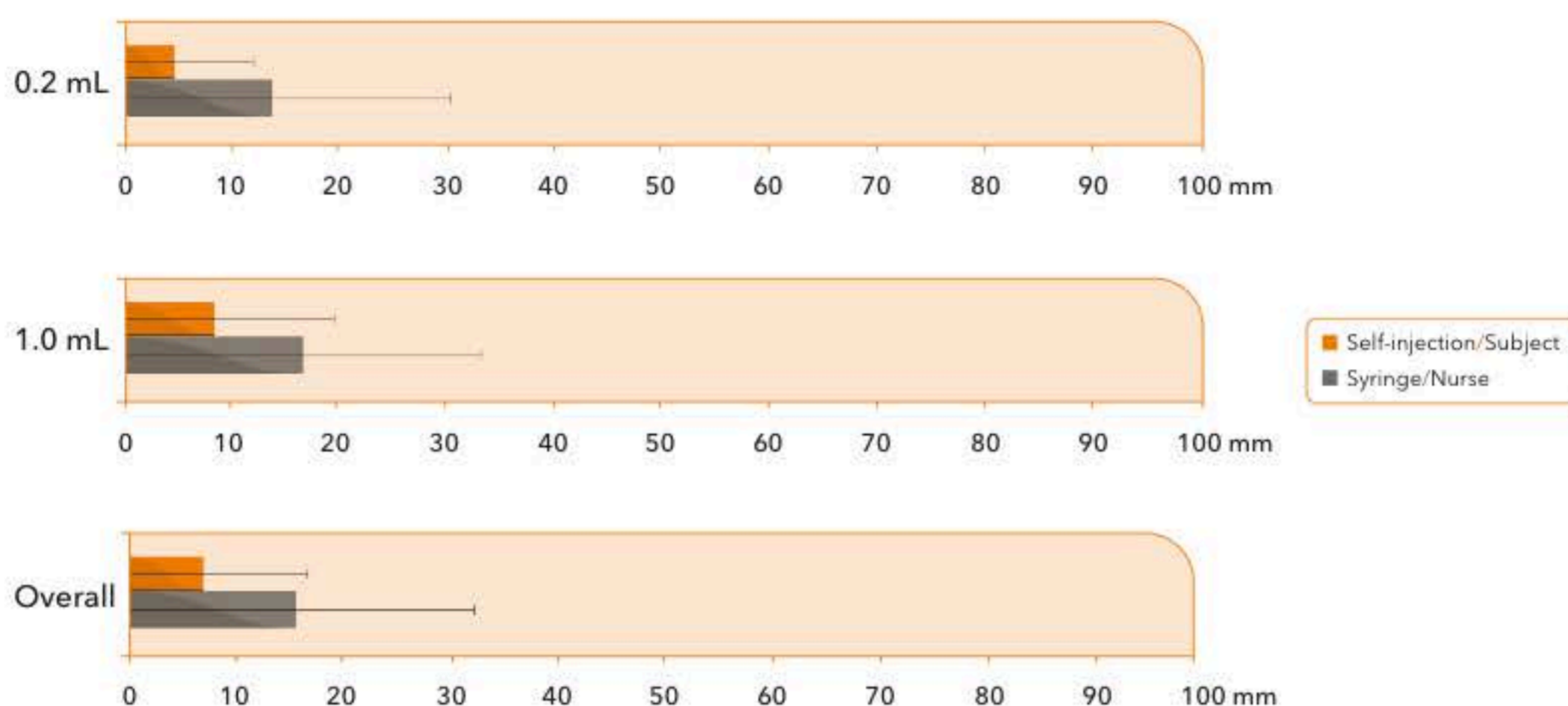


Figure 1. Study design

- A randomized, single-center, crossover study comparing SC self-injection using an autoinjector with SC nurse-administered injection using a syringe.
- Each subject came for three separate sessions of eight injections. The order of injections was balanced across all subjects in terms of the system, volume, and injection site, and subjects were randomly assigned to a prespecified order of injection (Figure 1).
- Pain measured by a VAS (Visual Analog Scale) immediately after each of the 960 injections.
- Primary Endpoint: Fluid leakage and injected volume, gravimetric method.
- Secondary Endpoint: Perceived pain, 100 mm VAS.

## Autoinjector: Lower Pain, Higher Compliance



**Figure 2:** Subjects reported significantly less pain when injections were self-administered by the autoinjector than when given by nurses with the syringe ( $P < 0.0001$ ), and with an injection of 0.2 mL rather than 1.0 mL ( $P = 0.0003$ ).

Volume	System	N	Leakage ( $\mu\text{L}$ )		Injected volume ( $\mu\text{L}$ )	
			Mean (SD)	Median (MAD)	Mean (SD)	Median (MAD)
0.2 ml	Self-injection/subject	205	1.7 (2.4)	1.0 (1.0)	206.8 (8.0)	207 (4)
	Syringe/nurse	233	2.1 (2.6)	1.0 (1.0)	206.6 (5.8)	208 (2)
1 ml	Self-injection/subject	206	3.3 (17.5)	1.0 (1.0)	1013.0 (19.9)	1015 (4)
	Syringe/nurse	227	1.6 (2.0)	1.0 (1.0)	1012.0 (7.1)	1013 (3)
Total of analyzed injections		871				
Missing data		1 missing value for an injection by nurse 88 leakages were not collected				
Total of performed injections		960				

**Table 1:** There were no significant differences in mean fluid leakage and injected volumes between the autoinjector device and PFS.

- Fluid depot location in the hypodermis after injection showed no significant difference between 2 groups.
- Skin reactions were not significantly different between two groups; however, local edema was more frequent with injections by nurses. ( $p$  value  $< 0.0001$ )
- Patients preferred self-injection with autoinjector to an injection by a nurse.

**Reference:** Berteau C, Schwarzenbach F, Donazzolo Y, Latreille M, Berube J, Abry H, et al. Evaluation of performance, safety, subject acceptance, and compliance of a disposable autoinjector for subcutaneous injections in healthy volunteers. *Patient Prefer Adherence*. 2010;4:379-88.



شرکت تحقیقاتی و تولیدی سیناژن  
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