Clinical study summary (CSS)

CT registry ID#: NCT00139789
Study no.: SP843

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Proprietary drug name	INN	Therapeutic area and indication(s)
Kemstro™	Baclofen	Multiple sclerosis

Name of Sponsor/company: UCB

Title of study:
A multicenter, open-label randomized crossover trial to assess subject preference for Kemstro™ compared to conventional Baclofen tablets in subjects with stable multiple sclerosis.

Investigator(s) (number only):	10
Study center(s) (number only):	10

Length of study:		Phase of development:	Phase 3b
Date first patient enrolled:	07 Jan 2005		
Date last patient completed:	04 Apr 2005		

Abstract:
The objective of this trial was to assess subject preference for Kemstro vs conventional baclofen tablets in subjects with stable multiple sclerosis who were already taking baclofen for spasticity.

Following screening, eligible subjects were randomized to 1 of 2 treatment sequences: Kemstro followed by conventional baclofen, or conventional baclofen followed by Kemstro. The Subject Preference Questionnaire was administered after the subject had taken both conventional baclofen and Kemstro.

Safety and tolerability were assessed by evaluating adverse events (AEs), changes in oral cavity examinations, and vital signs.

Number of subjects:	Overall
Planned, N:	60
Enrolled, N:	60
Randomized, N:	59
Withdrawn due to adverse events, n (%):	0

Safety outcomes:
- Summary of treatment emergent adverse events, deaths, other serious adverse events and certain other significant adverse events:

Relatively few treatment-emergent AEs (TEAEs) were reported during the study, and only 1 was severe in intensity. No subject experienced serious adverse events (SAEs) or discontinued due to an AE. One subject experienced mild stomatitis of 1-day duration on the first day of treatment with Kemstro; the investigator considered the stomatitis to be highly probably related to the study drug. In general, the TEAEs reported during the study were unremarkable and there were no apparent treatment-related trends.

Vital sign measurements were unremarkable.

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Treatment-emergent AEs (TEAE):		
Subjects with TEAEs	**Treatment period**	
(by primary System Organ Class)	*Baclofen N=59*	*Kemstro N=59*
	n (%)	
Eye disorders	*0*	*1 (1.7)*
Gastrointestinal disorders	*1 (1.7)*	*2 (3.4)*
General disorders and administration site conditions	*0*	*1 (1.7)*
Infections and infestations	*2 (3.4)*	*3 (5.1)*
Nervous system disorders	*1 (1.7)*	*3 (5.1)*
Psychiatric disorders	*0*	*1 (1.7)*
Death and other SAEs:		
Death, n (%):	**0**	
Subjects with SAEs, n (%):	**0**	
Primary & secondary outcomes: While subjects preferred Kemstro to conventional baclofen regarding several aspects of treatment explored by the questionnaire, similar proportions of subjects expressed an overall preference for each formulation. The statistically significant responses in favor of Kemstro were related to quicker access, discreet use in public, and reduced concern about swallowing medication.		
Publication reference(s) based on the study: none		
Date of report: 19 Nov 2008		