

**Abstract Reproduction Form B-1**

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Title (type in  
CAPITAL  
LETTERS)METAANALYSIS OF TWO PLACEBO-CONTROLLED, RANDOMISED,  
DOUBLE-BLIND, MULTICENTRE CLINICAL TRIALS WITH TROSPIMUM  
CHLORIDE (SPASMO-LYT<sup>®</sup>) IN PATIENTS WITH DETRUSOR INSTABILITY.

**OBJECTIVE:** The aim of this metaanalysis was to compare the efficacy and tolerability of trospium chloride (TCI) and placebo on objective urodynamic variables and subjective variables symptomatic for detrusor instability, respectively.

**DESIGN OF THE CINICAL TRIALS:** The trial protocol of the two studies was comparable so that the data were appropriate to be pooled in a metaanalysis. Both studies were carried out in placebo-controlled, double-blind, multicentre design with two parallel groups in order to evaluate the effect of 20 mg TCI bid with regard to efficacy and tolerability. The studies considered and their population sizes are summarised below:

- MP94D2.03: n = 208 (TCI: 104, Placebo: 104)
- MP94D2.14: n = 309 (TCI: 210, Placebo: 99)

The treatment period in both studies was 21 days.

**METHODS:** The efficacy of TCI in 517 patients was evaluated by means of urodynamic measurements before and after treatment. Furthermore, efficacy and tolerability were assessed by investigators and patients on a qualitative, ordinal scale. Primary efficacy variables were *maximum cystometric bladder capacity* and *volume at first unstable contraction*.

**RESULTS:** The two studies showed comparable results concerning the primary variables for efficacy which were statistically significant and clinically relevant in both analyses, Intention-to-treat (ITT) (see table below) and Per-protocol (PP).

## Abstract Reproduction Form B-2

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		TCI		Placebo		Treatment effect [change (TCI minus placebo)] [ml]	p (U-Test)
		pre	post	pre	post		
Maximum bladder capacity [ml]	n	266		174		+ 61.1	< 0.001
	Mean	264.3	321.9	285.1	281.7		
	SD	132.8	151.8	146.5	148.6		
Volume at 1. contraction [ml]	n	231		152		+ 62.2	0.0001
	Mean	150.8	230.9	159.2	177.1		
	SD	125.8	158.4	137.4	133.1		

SD = standard deviation

The assessment of investigators and patients revealed an advantage for trospium chloride with regard to efficacy. The tolerability judgement of investigators and patients was comparable to placebo (see table below).

### Investigator's Assessment on Tolerability (ITT)

Assessment	Treatment group			
	Placebo		TCI	
	n	%	n	%
very good	97	52.2	144	50.5
good	72	8.7	102	35.8
moderate	10	5.4	23	8.1
poor	7	3.8	16	5.6

### Patient's Assessment on Tolerability (ITT)

Assessment	Treatment group			
	Placebo		TCI	
	n	%	n	%
very good	104	55.3	137	47.9
good	66	35.1	108	37.8
moderate	7	3.7	22	7.7
poor	11	5.9	19	6.6

**CONCLUSIONS:** The dose of 20 mg trospium chloride bid showed statistically significant and clinically relevant effects in patients with detrusor instability in both clinical trials. Furthermore, the investigators and patients' assessment of efficacy and tolerability revealed a clear benefit in favour of trospium chloride.