EARLY DETECTION AND TREATMENT OF INTER-COSTO-BRACHIAL NEURALGIA AFTER BREAST CANCER SURGERY: A MULTICENTER RANDOMIZED CONTROLLED CLINICAL TRIAL.

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Introduction

Neuropathic pain following mastectomy occurs in 8% to 70% of patients. [1] Diagnosing peripheral neuropathic pain (PNP) is challenging and diagnostic difficulties may delay appropriate analgesic therapy leading to chronic neuropathic pain.[2] This study assesses the efficacy of topical treatment with high concentration 179 mg capsaicin patch (HCCP) compared to pregabalin. There is no comparative effectiveness data in this indication.

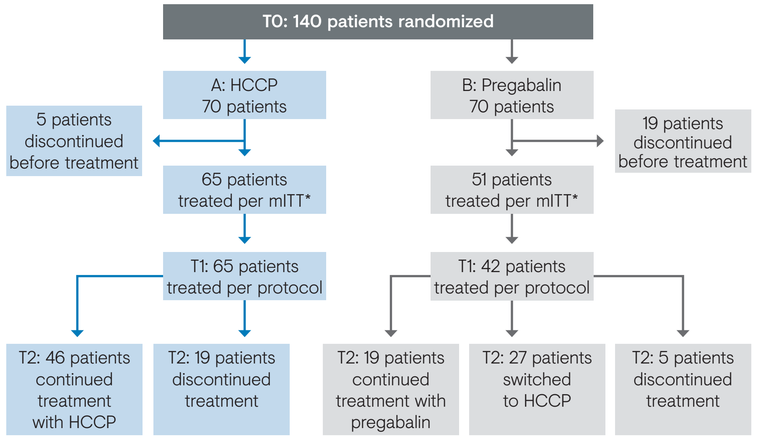
Methods

Consented patients with PNP and a first line surgical treatment for breast cancer <1 year ago, were randomized to HCCP applied at study sites or daily doses of up or 300 mg pregabalin. After 3 months, patients could continue/switch to the other treatment. Pain intensity was recorded on a numeric pain rating scale (NPRS), also measured were the painful area, the PGIC, EQ-5D and HADS. Tolerability was assessed. If at month 2, the upper limit of the confidence interval (CI) of the mean NPRS score with HCCP did not exceed the mean NPRS score for pregabalin +0.4, non-inferiority was concluded.

Results

The trial discontinued prematurely for COVID-19 reasons. In total 140 of 772 patients targeted, were randomized. All were female, most below age 65. Breast surgery was accompanied by radiotherapy, hormone therapy, adjuvant chemotherapy in >80%, >60% and approximately 30% respectively. Figure 1 shows the disposition. Table 1 displays the primary efficacy analysis (change from baseline in average pain intensity). There was no difference between treatments; the predefined non-inferiority criteria was met. Greater reduction of the mean painful area was observed with HCCP, compared to pregabalin (p=0.02) (Table 2). The tolerability profile was characterized by application site adverse events for HCCP and systemic adverse events for pregabalin. After 2 months, no HCCP patient switched to pregabalin, whereas 27/51 patients switched from pregabalin to HCCP.

Figure 1: Patient disposition



*mITT: modified intention-to-treat; T1 = Start of first treatment period; T2 = start of 2nd treatment period.

Table 1. Primary outcome: NPRS scores at Month 2 (PP population with missing data imputed)**

	Topical HCCP (n=65)	Oral pregabalin (n=42)
Randomisation (SD)	6 (1.5)	6.3 (1.7)
p-value for difference*	0.4506	
Month 2 (SD)	4.431 (2.487)	4.619 (2.905)
90% CI	3.892–4.908***	
p-value for difference*	0.8789	
Change from randomisation to Month 2 (SD)	−1.6 (2.4)	−1.9 (2.6)
p-value for difference*	0.522	

Data are mean (SD) unless stated otherwise.
* Difference between HCCP and pregabalin groups determined by ANOVA.
** The following rules were used for imputation: 1) if NPRS score was unavailable at baseline, the pre-inclusion NPRS score was taken, 2) if the NPRS was not available at Month 2, the score was imputed to 0 for the pregabalin arm and to the inclusion NRPS score for the HCCP arm.
*** the upper limit of the confidence interval with HCCP is 4.908 i.e. below the preset non inferiority margin of 4.619+0.4 (=5.19)
ANOVA, analysis of variance; CI, confidence interval; HCCP, high-concentration capsaicin patch; NPRS, Numeric Pain Rating Scale; SD, standard deviation.

Table 2. Secondary Endpoint : Painful area surface at randomisation and Month 2

	Topical HCCP (n=65)	Oral pregabalin (n=42)
Randomisation	115.3 cm^2 (±79)	130.8 cm^2 (±79.6)
p-value for difference*	0.3022	
Month 2	66.1 cm^2 (±49.9)	91.9 cm^2 (±63.3)
p-value for between group difference of change from randomisaton to Month 2*	0.02	

* Difference between HCCP and pregabalin groups determined by ANOVA.
ANOVA, analysis of variance; HCCP, high-concentration capsaicin patch.

Conclusions

Early diagnosis/treatment of PNP post-breast surgery are important and HCCP can be an effective alternative to oral treatment.

References
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