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Statistical Analysis Plan

Official title of study:

Effect of Topical Lidocaine on Warm and Cold Sensation in Healthy Individuals - a Randomized Crossover Trial

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Statistic TLH

Effect of Topical Lidocaine on Warm and Cold Sensation in Healthy Individuals

Endpoint	Description of endpoint	Statistic
Primary	Number PHS responders, original TSL, lidocaine compared to control	McNemar
Secondary	Number of TGI responders, lidocaine compared to control.	McNemar
	Strength of the TGI between TGI and non-TGI control stimuli	cold paired t-test/Wilcoxon warm paired t-test/Wilcoxon unpleasantness rating paired t-test/Wilcoxon pain rating paired t-test/Wilcoxon
	Number of PHS and TGI responses at baseline, i.e. without any treatment	McNemar
Tertiary	QST active vs control	CDT paired t-test/Wilcoxon WDT paired t-test/Wilcoxon CPT paired t-test/Wilcoxon HPT paired t-test/Wilcoxon MDT paired t-test/Wilcoxon MPT paired t-test/Wilcoxon
	Number of PHS responders using the TSL_QST vs mTSL	McNemar
	warm detection threshold when warming or cooling the skin prior to test vs baseline	nTSL paired t-test/Wilcoxon
	cold detection threshold when warming or cooling the skin prior to test vs baseline	paired t-test/Wilcoxon
	Number of PHS when warming or cooling the skin prior to test vs baseline	McNemar