HUM00189911 Optimization of TEA Modalities for Treatment of IBS-C

Visit # (1-5) 1 SUBJECT ID: 1001 VISIT DATE: 7/27/21

DATE INFOMRED CONSENT SIGNED: 7/27/21 Drawing Code: ____

Demographics

Sex: ☐ M ☑ F Year of birth: 2001 Height: 5 ft 7 in Weight: 160 lbs	
Race: ☐White ☑Black or African American ☐Native Hawaiian or Other Pacific Islander ☐Asian ☐American Indian or Alaska Native ☐Unknown	**Ethnicity:** ☐Hispanic or Latino ☑Not Hispanic or Latino ☐Unknown

Informed Consent Process

Initials and Date:
We discussed the study and its goals as well as the risks and requirements of TEA w/ Barastch. The subject gave her informed consent

Eligibility Criteria

Inclusion Criteria: In order to be eligible to participate in this study, a study participant must meet all of the following criteria:	
☑ Yes ☐ No	Male or female, aged 18 to 99
☑ Yes ☐ No	Willing to comply with all study procedures and be available for the duration of the study
☑ Yes ☐ No	Diagnosed with IBS-C satisfying Rome IV criteria (Survey completed by subject)
☑ Yes ☐ No	Have symptoms present for at least the last 3 months
☑ Yes ☐ No	Have abdominal pain that is not adequately relieved at the time of screening and the time of randomization
☑ Yes ☐ No	Has a VAS pain score of >3 (on 0-10 score)

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Rome IV Criteria for IBS	
Recurrent abdominal pain on average at least 1 day/week in the last 3 months related to defecation.	☑ Yes ☐ No
Recurrent abdominal pain on average at least 1 day/week in the last 3 months associated with a change in frequency of stool.	☑ Yes ☐ No
Recurrent abdominal pain on average at least 1 day/week in the last 3 months associated with a change in form (appearance) of stool.	☑ Yes ☐ No

Exclusion Criteria: A potential study participant who meets <u>any</u> of the following exclusion criteria at baseline will be excluded from participation in this study if:	
☐ Yes ☑ No	Have an unrelated active disorder which may involve abdominal pain, such as inflammatory bowel disease, diabetes, unstable thyroid disease
☐ Yes ☑ No	Have history of abdominal surgery (other than cholecystectomy or appendectomy)
☐ Yes ☑ No	Are taking anticoagulants or antispasmodic, antidiarrheal, or opioids or other pain relief medications and cannot stop these medications for three consecutive days before each study visit
☐ Yes ☑ No	Are pregnant or lactating; women of childbearing potential complete a pregnancy test at each visit
☐ Yes ☑ No	Have known allergic reactions to components of the ECG electrodes
☐ Yes ☑ No	Received treatment with an investigational drug or other intervention *within 6 months of the date of consent*
☐ Yes ☑ No	Anything that, in the opinion of the investigator, would place the study participant at increased risk or preclude the study participant's full compliance with or completion of the study
☐ Yes ☑ No	Are unable to provide informed consent

For women only:

Hysterectomy: ☐ Yes ☑ No	Post-Menopause*: ☐ Yes ☑ No
(If no to both of above) Pregnancy test result: ☐ Positive ☑ Negative	**Post-menopausal is defined as no menses for the previous 12 months. If cessation of menses is within 18 months then the subject should be treated as pre-menopausal and a pregnancy test must be performed.*

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The subject is eligible (meets all of the inclusion criteria and meets none of the exclusion criteria)
☑ True ☐ False

Procedure monitoring

Subject has not taken medications affecting the gut or pain perception for 48 hours. (anticoagulants, antispasmodic, antidiarrheal, opioids)	Subject has not had any food or drink other than water since 8 am	TEA Methods: ST36-100Hz ST36-25Hz (PC6-100Hz) PC6-25Hz SM-25Hz	EKG Settings: Frequency and Amplification
☑ True ☐ False	☑ True ☐ False	PC-6 100Hz	Frequency: 1.5Hz Amplification: 1000

15 Minute Baseline EKG (no Stimulation or Distention)

Time of Baseline Period Start:	3:05
Time of Baseline Period End:	3:20
Baseline EKG Recording Filename:	01-A-1
Baseline Recording Folder:	

Rectal Distention One without~~(no S~~stimulation~~)~~

Time of Barostat Catheter Insertion:	~~3:26~~ 3:23
Time of ~~First~~ Distention Initiation:	3:33
Time of ~~First~~ Distention Termination:	3:40
Distention One EKG Recording Filename:	01-A-2
Distention One EKG Recording Folder:	

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Rest Period

NA

Time of Rest Period Start:	/
Time of Rest Period End:	

CB 7-27-21

15 Minute Baseline EKG with Stimulation but no Rectal Distention

Time of Baseline Period Start:	3:49
Time of Baseline Period End:	4:05
Baseline EKG Recording Filename:	01-A-3
Baseline EKG Recording Folder:	

TEA/Sham TEA Administration

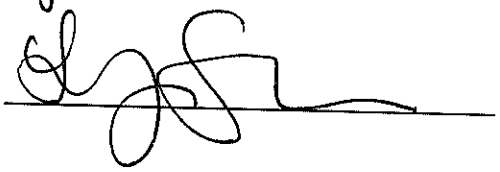
Time of TEA/Sham Initiation: 3:49 Time of change in output: 4:01 Time of change in output: Time of change in output:	Stimulation output (mA): 1.60 Stimulation output (mA): 1.85 Stimulation output (mA): Stimulation output (mA):

Rectal Distention Two (with stimulation)

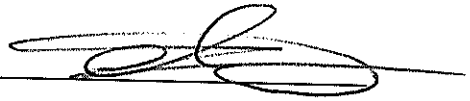
Time of ~~First~~ Distention Initiation:	4:09
Time of ~~Last~~ Distention Termination:	4:17
Time of Barostat Catheter Removal:	4:19
Distention Two EKG Recording Filename:	01-A-4
Distention Two EKG Recording Folder:	

CRA Signature: _____ Date: ___/___/___

Name of Person who performed the procedure: Lydia Watts

Signature of Person who performed the procedure: 

Date: 07/27/2021

PI Signature 

Date: ___/___/___

CRA Signature: _____ Date: ___/___/___

CUMULATIVE ADVERSE EVENTS

At end of study only: check this box if subject experienced NO ADVERSE EVENTS ☐

Adverse Event Reported Date	Adverse Event Description	Event Onset Date	Event End Date	Severity (Grade)	Attribution	Reported as SAE?	Outcome	Med taken	Comments (include CRA dated initials for each event)
/		/	/						
/		/	/						
/		/	/						

Severity (Grade)	Attribution: Relation to Study Agent	Reported as SAE?	Outcome
1 = mild 2 = moderate 3 = severe 4 = life-threatening 5 = fatal	1 = unrelated 2 = unlikely 3 = possible 4 = probable 5 = definite	1 = yes 2 = no	1 = resolved 2 = resolving 3 = not resolved 4 = resolved with sequelae 5 = fatal 6 = unknown

CRA Signature: _____ Date: ___/___/___