HUM00189911 Optimization of TEA Modalities for Treatment of IBS-C

Visit # (A-E) E SUBJECT ID: 1001 VISIT DATE: 8/31/21

DATE INFOMRED CONSENT SIGNED: ___/___/___ Drawing Code: _____

Demographics

Sex: □ M □ F Year of birth: ___ Height: ___ ft ___ in Weight: ___ 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:

Eligibility Criteria

Inclusion Criteria: In order to be eligible to participate in this study, a study participant must meet <u>all</u> 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)

CRA Signature: _____ Date: 8/31/21

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.*

CRA Signature: _____ Date: ___/___/___

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	ST 36 25Hz	Frequency: 1.5Hz Amplification: x1000

15 Minute Baseline EKG without Stimulation or Distention

Time of Baseline Period Start:	1220
Time of Baseline Period End:	1235
Baseline EKG Recording Filename:	01-E-1
Baseline Recording Folder:	

Rectal Distention One without Stimulation

Time of Barostat Catheter Insertion:	1241
Time of Distention Initiation:	12:45
Time of Distention Termination:	12:51
Distention EKG Recording Filename:	01-E-2
Distention EKG Recording Folder:	

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Rest Period

N/A

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

15 Minute Baseline EKG with Stimulation but no Rectal Distention

Time of Baseline Period Start:	1255
Time of Baseline Period End:	1:10
Baseline EKG Recording Filename:	01-E-3
Baseline EKG Recording Folder:	

TEA/Sham TEA Administration

Time of TEA/Sham Initiation: 1255 Time of change in output: 1:05 Time of change in output: Time of change in output:	Stimulation output (mA): 1.80 Stimulation output (mA): 2.20 Stimulation output (mA): Stimulation output (mA):

Rectal Distention Two with Stimulation

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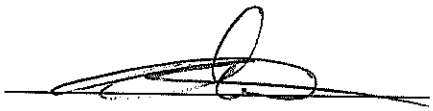
Time of Distention Initiation:	~~1:11~~ 1:12	
Time of Distention Termination:	1:22	
Time of Barostat Catheter Removal:	1:23	
Distention EKG Recording Filename:	01-E-4	
Distention EKG Recording Folder:		

CRA Signature: _____ Date: 8/31/21

Name of Person who performed the procedure: Lydia Watts

Signature of Person who performed the procedure: _____

Date: 8/31/21

PI Signature 

Date: 8/31/21

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: ___/___/___