Pilot Study

- **Objective:** To investigate the feasibility, acceptability, safety and efficacy of CRet diathermy in reducing pain and improving sexual function and quality of life in females diagnosed of chronic pelvic pain syndrome (CPPS).
- **Study Design**: The study will be a single-arm, observational, prospective feasibility study.
- **Study population and sample:**
  - ✓ Our study population will be females over 18 years of age, diagnosed with CPPS.
  - ✓ An a priori power analysis based on the difference between two dependent means indicated that primary outcome data for a sample size of n = 34 would be needed to achieve 80% power to detect a medium effect size (Cohen's d = 0.5, α = 0.05, 1 – β = 0.8, two-tailed hypothesis).
  - ✓ For the same population sample, the power to detect a large effect size (d ≥ 0.8) increases to 99%.
  - ✓ 38 patients will be recruited into the study to accommodate a maximum of 10% drop out rate.

Inclusion Criteria

- Female.
- Over 18 years of age.
- Diagnosed of CPPS, according to the definition by the European Urology Association (EUA) (Engeler et al. 2014).
- Presence of tenderness on palpation of LA muscle during vaginal examination.
- Presence of abnormal tension and instability at rest within the PFM as indicated by surface electromyographic (EMG) signal.
- Pharmacological treatment has remained stable for a minimum of 4 weeks prior to initiation of CRet therapy.
- Able and willing to give informed consent.

Outcome Measures

Primary Outcomes

- Visual Analogue Scale (VAS) 100 mm. Provide data on pain intensity only.
- McGill Pain Questionnaire. Provides valuable information on the sensory, affective and evaluative dimensions of pain experience.

Secondary outcomes

- PFM sEMG activity. Mean PFM activity over a minimum period of 100 secs (measured in μV).
- Female Sexual Function Index (FSFI) Consists on 19 six-point questions across six domains: desire, arousal, lubrication, orgasm, satisfaction, and pain.
- WHOQOL-BREF. It produces a quality of life profile. It is possible to derive four domain scores (physical health; psychological; social; environment). It helps to determine changes in quality of life over the course of interventions.
- Global Response Assessment. 7-point Likert scale (very much worse; much worse; a little worse; no change; a little better; much better; very much better).

Pilot Protocol

6 sessions - one session per week

- Week 1-3
  - ✓ 15’ External application with static-automatic electrodes.
  - ✓ 15’ Application of intracavitary electrode in static-automatic mode.
- Week 4-6
  - ✓ 10’ External application with static-automatic electrodes.
  - ✓ 20’ Application of static-automatic intracavitary electrode.
- Mean energy transmitted during abdominal external application: ***11537 J.***
- Mean energy transmitted during intravaginal application: ***24398 J.***

Pilot Protocol

6 sessions - one session per week

- Week 4.
  - ✓ 10’ External application with static-automatic electrodes.
  - ✓ 10’ Static application of static-automatic intracavitary electrode.
  - ✓ 10’ Dynamic application of static-automatic intracavitary electrode.
- Week 5.
  - ✓ 10’ External application with static-automatic electrodes.
  - ✓ 20’ Dynamic application of static-automatic intracavitary electrode.
- Week 3.
  - ✓ 10’ External application with static-automatic electrodes.
  - ✓ 20’ Dynamic application of static-automatic intracavitary electrode.

Results (interim)

22 subjects recruited until 26th July 2018

Mean (±sd) age ***35.1 (±8.4)*** years.

Mean BMI ***21.7 (± 4.1).***

Median (IQR) parity ***0.0 (1.0)***

Median duration of symptoms ***24 (99)*** months.

- 20 subjects have completed the 6-week course of treatment and have been reviewed a week after the last TECAR session.
- 15 subjects have attended a follow-up appointment 6 weeks after their last TECAR session.

Results (interim)

Outcomes 1 week after completing 6-week course

- **VAS:** Mean (±sd) reduction in VAS scores -50.5 (±25.8). 95% CI of the difference -62.9 to -38 ($p < 0.005$). Cohen's d: 1.95 (*Very large effect*)
- **McGill Pain Rating Index:** Mean reduction -12.3 (±12.3). 95% CI of the difference -18.8 to -6.5 ($p < 0.005$). Cohen's d: 1.0 (*Large effect*)
- **FSFI Full Scale Score:** Mean improvement 7.2 (±11.3). 95% CI of the difference 1.1 to 12.8 ($p = 0.02$). Cohen's d: 0.63 (*Medium effect*)
- **PFM sEMG activity.** Mean reduction -5.1 (±3.1). 95% CI of the difference -6.5 to -3.6 ($p< 0.005$). Cohen's d: 1.64 (*Very large effect*)
- **Physical Health subdomain of Quality of Life.** Mean improvement 15.2 (±15.4). 95%CI of the difference 7.9 to 22.4 ($p < 0.005$). Cohen's d: 0.98 (*Large effect*).

Results (interim)

Outcomes at 6-week follow-up still significantly improved both clinically and statistically

- **VAS** : Mean (±sd) reduction in VAS scores -51.9 (±29.4). 95% CI of the difference -68.2 to -35.6 ($p < 0.005$).
- **McGill Pain Rating Index:** Mean reduction -13.8 (±12.0). 95% CI of the difference -20.2 to -7.3 ($p < 0.005$).
- **FSFI Full Scale Score:** Mean improvement 9.2 (±9.7). 95% CI of the difference 3.3 to 15.81($p = 0.005$)
- **PFM sEMG activity.** Mean reduction -6.5 (±4.3). 95% CI of the difference -8.8 to -4.1 ($p< 0.005$).
- **Physical Health subdomain of Quality of Life.** Mean improvement 19.4 (±18.2). 95%CI of the difference 9.3 to 29.5 ($p = 0.001$).