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The efficacy and safety of temperature-controlled radiofrequency for the treatment of vaginal laxity in Chinese postpartum women

Submission date
15/07/2024

Recruitment status
No longer recruiting

Registration date
18/07/2024

Overall study status
Completed

Last Edited
17/07/2024

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Vaginal laxity (VL) is a common type of pelvic floor dysfunction disorder in women, associated with factors such as age, hormones, and childbirth, and it is frequently seen in postpartum women. Currently, vaginal tightening surgery is a more widely used clinical treatment method, but it is invasive. In recent years, non-invasive treatment methods including temperature-controlled radiofrequency (TCRF) have become the primary choice for patients seeking treatment. Radiofrequency can produce a heating effect that stimulates fibroblasts to generate new collagen and elastic fibers, improving local blood circulation, thereby achieving vagina tightening and vulva rejuvenating. However, there are currently few studies on the treatment of postpartum VL in Chinese women using this new TCRF device. This study aims to determine if the treatment is effective and safe for new mothers with VL by comparing it to sham (control) treatments. The study will include multiple locations, randomly assign participants, and keep the women unaware of which treatment they receive.

Who can participate?
Premenopausal women over the age of 18 with a history of at least one full-term vaginal delivery

What does the study involve?
Participants will be randomly assigned to either the TCRF treatment group or the sham control group. In this study, participants will not be informed about the status of the radiofrequency device's energy application, ensuring a blinded assessment of the treatment's effects. Radiofrequency thermotherapy device (SL ThermiRF I), with treatments administered once every three weeks for a total of three sessions, both vaginal and external genital areas are treated for 20-30 minutes each session, with a treatment temperature range of 35 to 42 (±3).

What are the possible benefits and risks of participating?
Participants may experience a reduction in VL, leading to enhanced sexual satisfaction and overall quality of life. However, it is essential to be aware of potential risks, such as discomfort, pain, swelling, and injection at the treatment site.

Where is the study run from?
The study was conducted at four sites in China, including Beijing Tsinghua Changgung Hospital (China)

When is the study starting and how long is it expected to run for?
September 2021 to December 2023

Who is funding the study?
Shandong Silin Pharmaceutical Technology Co., Ltd

Who is the main contact?
Dr Hui Shao, sh.2020@tsinghua.org.cn

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
SDSLSPRLY2023/1.0

Study information

Scientific Title
A prospective randomized controlled clinical study on the treatment of postpartum vaginal laxity in women with a novel temperature-controlled radiofrequency technology

Acronym
TTCRF

Study objectives
Transcutaneous temperature-controlled radiofrequency (TTCRF) treatment is more effective in improving vaginal laxity compared to a sham control.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 24/02/2022, Ethics Committee of the Chinese People's Liberation Air Force Medical Center (No.30 Fu-cheng Road, Haidian District, Beijing, 100142, China; +86 010-66928575; kjtsll@126.com), ref: AF-07.08/03.3

2. Approved 18/03/2022, Ethics Committee of Beijing Tsinghua Changgeng Hospital (NO.168 Litang Road Changping District, Beijing, 102218, China; +86 010-56118567; IRB@btch.edu.cn), ref: 22191-2-01

3. Approved 18/04/2022, Medical Ethics Committee of Beijing Obstetrics and Gynecology Hospital, Capital Medical University (No. 201 Community Service Center, Tuanjiehu Street, Wutaio, Tuanjie Hubei, Beijing, 100026, China; +86 010-85968407; fcyylunli@163.com), ref: IEC-C29-V02-FJI

4. Approved 25/03/2022, Ethics Committee of Beijing Friendship Hospital, Capital Medical University (No. 95 Yong'an Road, Xicheng District, Beijing., Beijing, 100050, China; 010-63139850; yd277@126.com), ref: 2022-P1--005-01

Primary study design
Interventional

Study design
Randomized prospective sham-controlled multicenter clinical trial

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Treatment of vaginal laxity in Chinese postpartum women

Interventions
This will be a randomized, sham-controlled clinical trial involving women diagnosed with vaginal laxity. Participants will be randomly assigned to either the temperature-controlled radiofrequency (TCRF) treatment group or the sham control group. Randomization will be conducted using a computer-generated random sequence using a central randomization system for dynamic enrollment of participants. An Interactive Web Response System (IWRS) automatically assigns participants to groups based on the order of enrollment. The study employs stratified block randomization by center, maintaining a 1:1 ratio of participants in the treatment group to the control group.

Radiofrequency thermotherapy device (SL ThermiRF I), with treatments administered once every three weeks for a total of three sessions, both vaginal and external genital areas are treated for 20-30 minutes each session, with a treatment temperature range of 35 to 42 (±3). The expected duration of the study for each subject is approximately 20 weeks, including a screening period of up to 2 weeks and a follow-up period of 18 weeks.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Radiofrequency thermotherapy device (SL ThermiRF I)

Primary outcome(s)
The change in FSFI total scores is measured at baseline and at 12 weeks post-treatment for the intervention group, and at baseline and 12 weeks post-final sham treatment for the control group

Key secondary outcome(s)
1. Sexual functioning measured using the Female Sexual Function Index (FSFI) questionnaire at weeks 3 and 6 post-initial treatment, and week 4 post-final treatment
2. Distress associated with impaired sexual function measured using the Female Sexual Distress Scale-Revised (FSDS-R) scale at weeks 3 and 6 post-initial treatment, and weeks 4 and 12 post-final treatment
3. The perception of vaginal laxity/density measured using the Vaginal Laxity Questionnaire (VLQ) at weeks 3 and 6 post-initial treatment, and weeks 4 and 12 post-final treatment
4. Sexual satisfaction from vaginal intercourse measured using the Sexual Satisfaction Questionnaire (SSQ) at weeks 3 and 6 post-initial treatment, and weeks 4 and 12 post-final treatment
5. Vaginal pressure change (resting and contractile pressures) measured using a perineometer at weeks 3 and 6 post-initial treatment, and weeks 4 and 12 post-final treatment
6. The degree of vaginal laxity measured using a digital assessment at weeks 3 and 6 post-initial treatment, and weeks 4 and 12 post-final treatment
7. Labial base length measured using a vernier caliper at weeks 3 and 6 post-initial treatment, and weeks 4 and 12 post-final treatment
8. Pigmentation will be evaluated by comparing baseline and post-treatment photographic records to identify any improvements. Elasticity will be scored using a tactile assessment ranging from 0 (indicating normal elasticity) to 3 (indicating poor elasticity). The assessments will be conducted at weeks 3 and 6 post-initial treatment, and weeks 6 and 12 post-final treatment.

Completion date
29/12/2023

Eligibility

Key inclusion criteria
1. Capable of understanding and voluntarily signing an informed consent form
2. Premenopausal women who are ≥18 years old
3. Have had at least one full-term vaginal delivery (>36 weeks of gestation) and are ≥12 months postpartum at the time of enrollment in this study
4. In the VLQ, the subject's self-perceived degree of vaginal laxity during intercourse is rated as "very loose," "loose," or "somewhat loose," and the degree of vaginal laxity measured by the researcher's digital examination is rated as "severe," "moderate," or "mild"
5. Cervical cytology results are normal
6. Willing to engage in vaginal intercourse at least once a week (note: this does not apply to situations where the subject must abstain from vaginal intercourse for at least one week after each study treatment)

7. Maintained a monogamous, heterosexual relationship for at least 6 months before study screening
8. The subject has a reasonable expectation, is capable of understanding, and can comply with the study procedures and all scheduled visit times
9. Women of childbearing age agree to use contraception throughout the study period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
150

Key exclusion criteria
1. Pregnancy, planning to become pregnant during the study period, or have given birth in the past 12 months
2. History of genital tract fistula, thin rectovaginal septum (approximately 1 cm or one finger width as assessed by the investigator), or history of fourth-degree perineal tear
3. Presence of an implanted cardiac pacemaker, any other implanted electromagnetic device, or metal implants (except dental implants)
4. Concomitant sexual dysfunction or vaginismus that affects sexual activity
5. Severe or progressive diseases who, in the investigator's judgment, pose a serious risk by participating in this clinical trial
6. Uncontrolled or unstable hypertension as determined by the investigator
7. Inflammation or unhealed wounds on the vulva and/or vagina
8. History of psychiatric conditions that, in the investigator's judgment, may affect study compliance and evaluation (e.g., depression, anxiety, bipolar disorder)
9. Underwent vaginal tightening surgery within the past 5 years, pelvic radiofrequency or laser treatment within the past year, or plans to receive such treatments during the study
10. Any other condition deemed unsuitable for enrollment by the investigator

Date of first enrolment
24/02/2022

Date of final enrolment
11/08/2023

Locations

Countries of recruitment
China

Study participating centre
Chinese People's Liberation Air Force Medical Center
No.30 Fu-cheng Road, Haidian District
Beijing
China
100142

Study participating centre
Beijing Tsinghua Changgeng Hospital
NO.168 Litang Road, Changping District
Beijing
China
102218

Study participating centre
Beijing Obstetrics and Gynecology Hospital, Capital Medical University
No. 261 Yaojiayuan Road, Chaoyang District
Beijing
China
100026

Study participating centre
Beijing Friendship Hospital, Capital Medical University
No. 95 Yong'an Road, Xicheng District
Beijing
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100050

Sponsor information

Organisation
Tsinghua University

ROR

https://ror.org/03cve4549

Funder(s)

Funder type
Industry

Funder Name
Shandong Silin Pharmaceutical Technology Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository: https://edc.clinflash.com. The type of data stored is individual participant data (IPD) including demographic details, treatment received, and outcomes measured.

IPD sharing plan summary
Stored in non-publicly available repository