ISRCTN11575756 https://doi.org/10.1186/ISRCTN11575756

Exploring how gentle vaginal laser treatment may help women with pelvic floor problems

Submission date
15/11/2025

Recruitment status
No longer recruiting

Registration date
18/11/2025

Overall study status
Completed

Last Edited
18/11/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Pelvic floor dysfunction is a common condition in women that can cause symptoms such as a feeling of vaginal bulging, discomfort, and sexual difficulties. Many women want treatments that work but are not invasive. This study looks at whether a gentle laser treatment called non-ablative Er:YAG laser can improve the structure and function of the vagina in the short term. We are interested in whether the treatment can reduce the size of the vaginal opening, change vaginal length, or improve sexual function.

Who can participate?
Women diagnosed with pelvic floor dysfunction who meet the study's eligibility criteria.

What does the study involve?
Participants receive one to three laser treatment sessions. Measurements and questionnaires are completed before treatment, about 6–8 weeks after the first session, and again 6–8 weeks after the second session. We check changes in vaginal measurements, pelvic organ support, and sexual function, and monitor for any side effects.

What are the possible benefits and risks of participating?
The treatment may improve symptoms related to pelvic floor dysfunction, but this is not guaranteed. There may be mild side effects, which will be monitored during the study.

Where is the study run from?
RAP Barcelona (Spain)

When is the study starting and how long is it expected to run for?
January 2024 to January 2025

Who is funding the study?
RAP Barcelona (Spain)

Who is the main contact?
Inés Ramírez García (ines.ramirez@rapbarcelona.com)

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Inés Ramirez Garcia

ORCID ID
https://orcid.org/0000-0002-1058-0577

Contact details
Avinguda Diagonal 363, 3-2
Barcelona
Spain
08037
+34 677745765
inesrg@blanquerna.url.edu

Additional identifiers

Study information

Scientific Title
Anatomical and functional effects of non-ablative vaginal laser in women with pelvic floor dysfunction: a prospective single-arm interventional study

Acronym
NAVILAS

Study objectives
To evaluate short-term changes in vaginal hiatus, vaginal length, and sexual function following non-ablative laser therapy in women with PFD.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/01/2024, Ramon Llull University Ethics Committee -FCSB (Padilla, 326-332, Barcelona, 08025, Spain; +34 932533256; bsalutcer@blanquerna.url.edu), ref: 2024/01/01

Study design
A prospective single-arm pre-post interventional study

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

Health condition(s) or problem(s) studied
Pelvic floor dysfunction

Interventions
The intervention consisted of IncontiLase® and IntimaLase® protocols delivered with the SP DYNAMIS system (S/N 14003339), aiming for controlled mucosal heating to approximately 65 °C to promote tissue tightening and collagen remodeling. Two sessions were administered 6–8 weeks apart by experienced operators; analgesia was provided as needed, eye protection and antiseptic preparation were used, and standard post-procedure instructions were given. The total pulse energy delivered to the anterior wall, posterior wall, 360° region, and vulvar region was recorded per session. Safety was assessed clinically at each treatment and follow-up visit; transient post-procedural sensations (local warmth, mild stinging, watery discharge, transient vulvovaginal erythema/edema) were recorded separately from adverse events (persistent pain, dysuria, vaginal spotting, irritation, or vaginal/urinary tract infection).

Intervention Type
Procedure/Surgery

Primary outcome(s)
At baseline (prior to the first laser session), follow-up 1 (6–8 weeks after the first session), follow-up 2 (6–8 weeks after the second session):
1. The vaginal hiatus was assessed following the criteria set forth by the joint report of the International Continence Society and the International Urogynecological Association (ICS/IUGA) on terminology for female pelvic floor dysfunction
2. Total vaginal length was defined as the distance in centimeters from the posterior fornix to the hymen, with point C or D reduced to its normal position.

Key secondary outcome(s))
At baseline (prior to the first laser session), follow-up 1 (6–8 weeks after the first session), follow-up 2 (6–8 weeks after the second session):
1. Pelvic floor muscle strength was assessed by vaginal palpation using the Oxford scale
2. Sexual function was evaluated with the self-administered Female Sexual Function Index (FSFI), which assesses six domains (desire, arousal, lubrication, orgasm, satisfaction, pain)

Completion date
25/01/2025

Eligibility

Key inclusion criteria
1. Women self-reported symptoms of pelvic floor dysfunction, which could include urinary incontinence, pelvic organ prolapse, or sexual dysfunction.
2. They perceived vaginal laxity, defined as a score of 4 or higher on the Vaginal Laxity Questionnaire (VLQ).
3. They were able to complete validated questionnaires used in the study.
4. They provided written informed consent to participate.
5. They authorized the use of their anonymized clinical data for research purposes.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
Female

Total final enrolment
163

Key exclusion criteria
1. Previous vaginal laser therapy
2. Contraindications to non-ablative vaginal laser
3. Concomitant interventions expected to confound outcomes during the evaluation period, such as pelvic floor physiotherapy, vaginal radiofrequency, or other concurrent treatments

Date of first enrolment
27/01/2024

Date of final enrolment
03/10/2024

Locations

Countries of recruitment
Spain

Study participating centre
RAPbarcelona SL
Avinguda Diagonal 363, 3-2
BARCELONA
Spain
08037

Sponsor information

Organisation

RAPbarcelona, Spain

Funder(s)

Funder type
Not defined

Funder Name
RAPbarcelona

Funder Name
The Faculty of Health Sciences Blanquerna- Ramon Llull University

Results and Publications

Individual participant data (IPD) sharing plan
Available on request. The datasets generated and analysed during the current study will be available upon request from Prof. In (és Ramírez-García (inesrg@blanquerna.url.edu); type of data: all raw data; timing. not yet known; consent obtained: yes; anonymiztion: coded /anonymous; restrictions: none; additional comments: none

IPD sharing plan summary
Available on request