

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

Submission date 15/11/2025	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/11/2025	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 18/11/2025	Condition category Musculoskeletal Diseases	☐ Individual participant data ☒ 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

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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

Primary study design

Interventional

Study design

A prospective single-arm pre-post interventional study

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. Inés Ramírez-García (inesrg@blanquerna.url.edu); type of data: all raw data; timing: not yet known; consent obtained: yes; anonymization: coded /anonymous; restrictions: none; additional comments: none

IPD sharing plan summary

Available on request