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Non-ablative laser in genitourinary menopause syndrome

Submission date
25/08/2025

Recruitment status
No longer recruiting

Registration date
31/08/2025

Overall study status
Completed

Last Edited
27/08/2025

Condition category
Urological and Genital 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
Genitourinary syndrome of menopause (GSM) negatively impacts quality of life in postmenopausal women. This study aimed to evaluate the effects of non-ablative Er:YAG laser therapy on anatomical, functional, and subjective outcomes in women with GSM.

Who can participate?
Postmenopausal women with GSM

What does the study involve?
Participants underwent two sessions of non-ablative vaginal laser (IncontiLase® and IntimaLase®). Clinical evaluations were performed at baseline, first follow-up, and second follow-up. Instruments included sexual functions, incontinence, quality of life, and pelvic health

What are the possible benefits and risks of participating?
Participants may benefit from a potential reduction of symptoms related to GSM, such as improvement in vaginal anatomy, reduction in cystocele, and enhancement in certain quality-of-life domains (e.g., social embarrassment, psychosocial impact, and behavioral limitations). Some women may also experience a decrease in pain during sexual activity.

The risks associated with participation are minimal, as the procedure involves non-ablative Er:YAG laser therapy. Possible adverse effects may include temporary discomfort, mild vaginal irritation, or transient changes in arousal. No major complications have been reported in previous studies, and the intervention is considered safe.

Where is the study run from?
RAPbarcelona, 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?
1. RAPbarcelona, Spain, supports the research

2. The Faculty of Health Sciences Blanquerna – Ramon Llull University will support review, translation, and publication costs

Who is the main contact?
Prof Inés Ramírez-García, inesrg@blanquerna.url.edu, iraga73@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Impact of non-ablative Er:YAG laser on genitourinary menopause syndrome: prospective interventional study

Acronym
NALinGMS

Study objectives

Genitourinary syndrome of menopause (GSM) negatively impacts quality of life in postmenopausal women. This study aimed to evaluate the effects of non-ablative Er:YAG laser therapy on anatomical, functional, and subjective outcomes in women with GSM.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/01/2024, Ramon Llull University Research Ethics Committee (CER)-FCSB (Padilla, 326-332, Barcelona, 08025, Spain; +34 93 253 32 56; bsalutcer@blanquerna.url.edu), ref: 2024/01/01

Study design
Prospective single-arm pre-post interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other therapist office

Study type(s)
Quality of life, Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Genitourinary menopause syndrome

Interventions
Each subject underwent treatment using the IncontiLase® and/or IntimaLase® protocols, delivered through a non-ablative Er:YAG laser device (model SP DYNAMIS, S/N 14003339). The laser applies controlled photothermal energy to elevate epithelial temperatures to approximately 65°C, promoting collagen remodeling and mucosal tightening. Two sessions were scheduled per participant with an intersession interval of 6–8 weeks. A third session was prescribed selectively, based on individual clinical progression and medical criteria.

Intervention Type
Procedure/Surgery

Primary outcome measure
Vaginal anatomical outcomes (Anatomical assessments involved measuring vaginal hiatus and total vaginal length) measured using a Sims speculum to retract vaginal walls and enable direct visualization. The vaginal hiatus was recorded as the maximal transverse distance between the vaginal borders during a Valsalva maneuver, and total vaginal length was measured from the posterior fornix to the hymenal ring, with manual repositioning of point C or D when required.

These measures were conducted at three specific time points. The baseline evaluation (EB) was performed before the first laser session. The first follow-up (FU1) took place between 6 and 8 weeks after the initial treatment, while the second follow-up (FU2) was scheduled 6 to 8 weeks after the second laser session.

Secondary outcome measures
The following secondary outcome measures were assessed at the baseline evaluation (EB) before the first laser session, the first follow-up (FU1) between 6 and 8 weeks after the initial treatment, and the second follow-up (FU2) 6 to 8 weeks after the second laser session:
1. Sexual function measured using the Female Sexual Function Index (FSFI)
2. Incontinence severity measured using the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF)
3. Quality of life measured using the Incontinence Quality of Life Questionnaire (I-QOL)
4. The pelvic floor strength measured using the Oxford Grading Scale for Pelvic Floor Muscle Strength

Overall study start date
01/01/2024

Completion date
25/01/2025

Eligibility

Key inclusion criteria
1. Treated at the participating unit
2. Presented with clinical manifestations of GSM such as vaginal dryness, dyspareunia, a sensation of laxity, urinary incontinence, or sexual dysfunction
3. Written informed consent obtained before enrollment

Participant type(s)
Patient

Age group
Mixed

Lower age limit
49.11 Years

Upper age limit
67.1 Years

Sex
Female

Target number of participants
47

Total final enrolment
47

Key exclusion criteria
1. Not having menopause or GMS
2. No written informed consent

Date of first enrolment
27/01/2024

Date of final enrolment
03/10/2024

Locations

Countries of recruitment
Spain

Study participating centre
RAPbarcelona
Avinguda Diagonal 263
Barcelona
Spain
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Sponsor information

Organisation
RAPbarcelona

Sponsor details
Avinguda Diagonal 363, 3-2
RAPbarcelona-Inés Ramírez
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08037

Sponsor type
Hospital/treatment centre

Website
https://rapbarcelona.com/

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
RAPbarcelona

Results and Publications

Publication and dissemination plan
Planned dissemination activities include the submission of the study results to peer-reviewed scientific journals related to pelvic health and physiotherapy, preferably indexed in JCR Q3 or Q4 (e.g., International Urogynecology Journal, Urogynecology, or JWPHPT). Additionally, results will be presented at relevant national and international conferences on pelvic floor rehabilitation, women's health, or physical therapy. Communication to clinical and academic communities will also be promoted through professional networks, institutional channels, and, when appropriate, social media platforms to enhance accessibility and impact.

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan
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