

TCTR ID : TCTR20191030001

Overall Recruitment Status : Completed (No Results)

OTHER ID :

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date : 30 October 2019
First Posted Date : 30 October 2019
Last Update Posted Date : 24 January 2023

Title

Public Title : Number of vaginal lactobacilli in postmenopausal women with vaginal atrophy before and after treatment with erbium YAG laser, a randomized sham-controlled trial
Acronym : No Data
Scientific Title : Number of vaginal lactobacilli in postmenopausal women with vaginal atrophy before and after treatment with erbium YAG laser, a randomized sham-controlled trial
Sponsor ID/ IRB ID/ EC ID : IRB 802/61
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20191030001>
Secondary ID : Other Grant/Funding Number; Grantor or Funder : RA62/071 RA62/071

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : IRB 802/61
Date of Approval : No Data
Board Name : Faculty of medicine, Chulalongkorn university, Ethics Committee
Board Affiliation : Faculty of medicine, Chulalongkorn university
Board Contact : Business Phone : 02-256-4455 Ext. No Data
Business Email : psinthavanuruk@yahoo.com
Business Address : 1873 Rama4 road Prathumwan Bangkok 10330

Sponsor

Source(s) of Monetary or Material Supports : Ratchadapisek Sompot Fund
Study Primary Sponsor : Ratchadapisek Sompot Fund
Responsible Party : Name/Official Title : Nuttanun Panyawongudom
Organization : Faculty of medicine, Chulalongkorn university
Phone : 0800690022 Ext. No Data
Email : nuttanun10134@gmail.com
Study Secondary Sponsor : Department of Obstetrics and Gynecology, Faculty of medicine, Chulalongkorn university

Protocol Synopsis

Protocol Synopsis : A Randomized sham-controlled study. The aim of the study is to evaluate the effect of vaginal erbium YAG laser on the number of vaginal lactobacilli in postmenopausal patients with moderate to severe vaginal atrophy. Vaginal erbium YAG laser is now the new option for the treatment of vaginal atrophy. Many previous non-randomized studies have suggest that vaginal erbium laser can improve vaginal atrophy symptoms and improve vaginal maturation index in postmenopausal women with moderate to severe vaginal atrophy. However, most of the previous studies were non-randomized studies and none of them evaluated the effect of vaginal erbium YAG laser on the number of vaginal lactobacilli

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Menopause Vaginal atrophy
Keywords : Erbium YAG laser Vaginal lactobacilli Randomized sham-controlled trial Menopause Vaginal atrophy Vaginal pH

Eligibility

Inclusion Criteria : Postmenopausal patients with moderate to severe vaginal atrophy
Age more than 40 years old

Gender : Female

Age Limit : Minimum : 40 Years Maximum : 90 Years

Exclusion Criteria : Use of hormonal treatment in previous 3 months
Use of vaginal lubricants or moisturizer in previous 3 months
Use of drugs which applied vaginally in previous 3 months
Use of spermicide in previous 3 months
Previous vaginal surgery in 3 months
Previous vaginal laser treatment
History of genitourinary tract infection in previous 1 months
Abnormal vaginal bleeding
Pelvic organ prolapse POP-Q stage at least 2

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates	Study Start Date (First enrollment) : 01 May 2019	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 30 September 2020	Indicate Type : Actual
	Study Completion Date : 30 September 2020	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 2

Intervention Model : Parallel

Number of Arms : 2

Masking : Masked Masked Role : Allocation concealment, Subject, Outcome Assessor,

Allocation : Randomized

Control : Placebo

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size : 42

Actual sample size at study completion : 44

Intervention Arm 1

Intervention name : vaginal erbium YAG laser

Intervention Type : Experimental

Intervention Classification : Procedure/Surgery

Intervention Description : vaginal erbium YAG laser (Fotona Smooth™ XS) wavelength 2940 nm monthly for 2 courses

Intervention Arm 2

Intervention name : sham laser

Intervention Type : Sham Comparator

Intervention Classification : No treatment

Intervention Description : sham vaginal laser: use the same device as intervention but release none of the erbium YAG laser

Outcome

Primary Outcome

1. Outcome Name : Effect of erbium YAG laser on the number of vaginal lactobacilli in postmenopausal women

Metric / Method of measurement : Vaginal gram stain

Time point : 2 months

Secondary Outcome

1. Outcome Name : vaginal atrophy symptoms

Metric / Method of measurement : visual analog scale

Time point : 2 months

2. Outcome Name : vaginal pH

Metric / Method of measurement : pH indicator strips

Time point : 2 months

Location

Section A : Central Contact

Central Contact	First Name : Nuttanun	Middle Name :	Last Name : Panyawongudom
	Degree : MD.	Phone : 0800690022 Ext. : No Data	Email : nuttanun10134@gmail.com
Central Contact Backup	First Name : Krasean	Middle Name :	Lastname : Panyakhamlerd
	Degree : MD., M.Sc.	Phone : 022564241 Ext. : No Data	Email : Fmedkpy@md2.md.chula.ac.th

Section B Facility Information and Contact

1. Site Name : Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn university

City : No Data

State/Province : Bangkok

Postal Code : 10330

Country : Thailand

Recruitment Status : Recruiting

Facility Contact First Name : Ammarin

Middle Name :

Last Name : Suwan

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Facility Contact Backup First Name : Krasean

Middle Name :

Last Name : Panyakhamlerd

Degree : MD., M.Sc.

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Investigator Name First Name : Nuttanun

Middle Name :

Last Name : Panyawongudom

Degree : MD.

Role : Principal Investigator

Section C : Contact for Public Queries (Responsible Person)

First Name : Krasean

Middle Name :

Last Name : Panyakhamlerd

Degree : MD., M.Sc.

Phone : 022564241 Ext. : No Data

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Postal Address : 1380 Nakornchaisri Rd, Dusit

State/Province : Bangkok

Postal Code : 10330

Country : Thailand

Official Role : Study Chair

Organization Affiliation : Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn university

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Ammarin

Middle Name :

Last Name : Suwan

Degree : MD.

Phone : 0819769422 Ext. : No Data

Email : whitelabor.sw@gmail.com

Postal Address : 1873 Rama4 Road, Patumwan

State/Province : Bangkok

Postal Code : 10330

Country : Thailand

Official Role : Study Chair

Organization Affiliation : Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn university

Summary Results

Date of posting of results summaries : Summary results not yet available

Date of first journal publication of results : Not yet published

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : Yes

Plan description : IPD and documents will be available for sharing 1 year after publication for a period of 2 years

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data