TCTR ID : TCTR20191030001 OTHER ID :

Overall Recruitment Status: Completed (No Results)

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 atrophyVaginal 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

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

Intervantion Arm 1

Intervention name: vaginal erbium YAG laser

Intervention Type: Experimental

Intervention Classification: Procedure/Surgery

Intervention Description: vaginal erbium YAG laser (Fotona SmoothTM XS) wavelength 2940 nm monthly

for 2 courses

Intervantion 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

Indicate Type: Actual

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:

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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

Degree: MD. Phone: +6619769422 Ext.: No Data Email: whitelabor.sw@gmail.com

Facility Contact Backup First Name: Krasean Middle Name: Last Name: Panyakhamlerd

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Fmedkpy@md2.md.chula.ac.th

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 Email :

Fmedkpy@md2.md.chula.ac.th

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