**TCTR ID : TCTR20191030001**

**Overall Recruitment Status :** Completed (No Results)

This protocol was registered after enrollment of the first participant.

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**Tracking Information**

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

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**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

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**Ethics Review**

1. **Board Approval:** Submitted, approved
2. **Approval Number:** IRB 802/61
3. **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

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**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

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**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**

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**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

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**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

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**Status**

<table>
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<tr>
<th>Key Trial Dates</th>
<th>Indicate Type</th>
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<tr>
<td>Study Start Date (First enrollment) : 01 May 2019</td>
<td>Actual</td>
<td>Completed</td>
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<tr>
<td>Completion Date (Last subject, Last visit) : 30 September 2020</td>
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<tr>
<td>Study Completion Date : 30 September 2020</td>
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**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 SmoothTM 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

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**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**
| Page 3/3 | This document was created on 15 October 2023 at 06:59 (GMT+7). |

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

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<thead>
<tr>
<th>Contact Type</th>
<th>First Name</th>
<th>Middle Name</th>
<th>Last Name</th>
<th>Phone</th>
<th>Email</th>
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<tbody>
<tr>
<td>Central Contact</td>
<td>Nuttanun</td>
<td></td>
<td>Panyawongudom</td>
<td>0800690022 Ext. No Data</td>
<td><a href="mailto:nuttanun10134@gmail.com">nuttanun10134@gmail.com</a></td>
</tr>
<tr>
<td>Central Contact Backup</td>
<td>Krasean</td>
<td></td>
<td>Panyakhamlerd</td>
<td>022564241 Ext. No Data</td>
<td><a href="mailto:Fmedkpy@md2.md.chula.ac.th">Fmedkpy@md2.md.chula.ac.th</a></td>
</tr>
</tbody>
</table>

### Section B Facility Information and Contact

1. **Site Name**: Department of Obstetrics and Gynecology, Faculty of Medicine, Chulalongkorn university  
   **City**: Bangkok  
   **State**: Bangkok  
   **Postal Code**: 10330

#### Facility Contact

<table>
<thead>
<tr>
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<tr>
<td>Ammarin</td>
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### Investigator Name

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#### Section C : Contact for Public Queries (Responsible Person)

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<thead>
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### Section D : Contact for Scientific Queries (Responsible Person)

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</tr>
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</table>

### Summary Results

- **Date of posting of results summaries**: Not yet published
- **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