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Compare the effect of two Ayurveda drug regimens on the treatment of uterine fibroids

Submission date
24/01/2019

Recruitment status
No longer recruiting

Registration date
11/02/2019

Overall study status
Completed

Last Edited
03/11/2021

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and aim of study:
Uterine fibroids called leiomyomas or myomas are the most common growth of the female womb. This growth (tumour) occurs in 20%–40% of childbearing age women, causing heavy menstrual bleeding, painful menstruation, and back pain. These problems can have a remarkable influence on women's health. To date, most treatments for fibroid has been surgical, either removing the growth or the whole womb (hysterectomy). Surgical interventions require general anesthesia, lengthy hospital stays, and long recovery periods, presenting hardships for women working at home and in the work force. Furthermore, hysterectomy does not allow women to preserve their fertility. Therefore women would prefer to have a benign uterine disease such as fibroids treated as conservatively as possible. In this context, various complementary and alternative medicine treatments have being used for uterine fibroids in clinical practice. Ayurveda is the most popular complementary medicine in Sri Lankan practice for non-surgical medical treatment of uterine fibroids. The aim of this study is to investigate whether the use of this selected two Ayurveda drug regimens over a period of 12 weeks is able to reduce the size of fibroids and associated features.

Who can participate?
Women aged 18 to 50 with uterine fibroids

What does the study involve?
Participants are randomly allocated to receive one of two Ayurveda treatments for 12 weeks, including oral drugs and external oil application. Volume of the largest fibroid is measured at the start and the end of the study (12 weeks).

What were the possible benefits and risks of participating?
The participants receive information and advice from a specialized medical team. In addition their participation helps to develop an Ayurveda drug treatment for uterine fibroids.

Where is the study run from?
National Ayurveda Teaching Hospital (Sri Lanka)

When is the study starting and how long is it expected to run for?
January 2017 to March 2020 (updated 11/11/2020, previously: February 2020)

Who is funding the study?
University Grants Commission (Sri Lanka)

Who is the main contact?
Dr Kaumadi Karunagoda
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016/ MPhil- PhD/ 037

Study information

Scientific Title
Randomized, single blind, clinical trial to compare the efficacy of selected two Ayurveda herbal regimens on the treatment of uterine fibroids

Study objectives
Two Ayurveda drug regimes are effective for the treatment of uterine fibroids.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Review Committee, Institute of Indigenous Medicine (ERCIIM), University of Colombo, Sri Lanka, Ethics Review Committee, Institute of Internal Medicine, University of Colombo, Rajagiriya, Sri Lanka, Tel: 094112692385, Email: ethicsreviewiim@gmail.com, 03/08/2017, No: ERC 17/68

Study design
Randomized single-blind three-arm clinical study

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
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
Uterine fibroids

Interventions
Included participants will be randomly allocated to Arm I and Arm II to receive Ayurveda treatment regimen with oral and external administration for 12 weeks. The drug regimen is the same for the initial 2 weeks, consisting of decoction Panchamooli Laghudrakshadi 30 ml, bd., before meals, chandraprabha 500 mg x 2 pills, bd., after meals and manibadra powder 5 g at night.

Then for the next 10 weeks Arm I will be treated with decoction (Thriphal gugul) 30 ml, bd., before meals, pancha tikta grita gugulu, 500 mg x 2 pills, and krishnajeeraka powder 5 g bd., after meals. 5 ml of Sarshapadi oil will be applied externally to lower abdomen for 7 days after cessation of menstruation.

Arm II will be treated with decoction (Punarnavashtaka) 30ml, bd., before meals, Kanchanara gugulu, 500mg x 2 pills, and Shatapushpa powder 5 g bd., after meals. 5 ml of Nirgundi oil will be applied externally to lower abdomen for 7 days after cessation of menstruation.

Arm III is a control group. They do not receive any intervention but monitoring will carried out by the investigator. Cases who are waiting for myomectomy or hystorectomy for uterine fibroids will be considered as they don't receive medicine in normal clinical setup.

USS was used to determine the primary outcome. Change from baseline in volume of the largest fibroid was measured with TVS/TAS at the end of 12 weeks (Visit 8) and again after one month at follow up (Visit 10). Changes from baseline in the Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire, effect of therapy according to the Ayurveda body constituent (Prakriti), and changes of the levels of the hormones estrogen (E2) and FSH will be studied by comparing before and after treatment values as secondary outcome measures.

Follow up - participants will be assessed at two-week intervals at the clinic without a drug intervention. Study participants will be followed up for four weeks after the drug administration period every 2 weeks. Associated features will be assessed in each visit and USS will be performed in the last visit (Visit 10).

Intervention Type
Mixed

Primary outcome measure

Volume of the largest fibroid measured using TVS/TAS at baseline and the end of intervention (12 weeks)

Secondary outcome measures
1. Health-related quality of life measured using Uterine Fibroid Symptom and Quality of Life (UFS-QOL) questionnaire at baseline and the end of the intervention (12 weeks)
2. Effect of the drug regimens according to the body constituents (Ayurveda body type) measured using questionnaire at the end of the intervention (12 weeks)
3. Changes of the serum hormone levels; estrogen (E2), FSH measured by serum investigations at baseline and at the end of intervention (12 weeks)

Overall study start date
30/01/2017

Completion date
25/03/2020

Eligibility

Key inclusion criteria
1. Women who are in reproductive age between 18 to 50 years
2. Ability to take medication and be willing to adhere to the medication regimen
3. Willing and able to give informed consent
4. Have at least one fibroid (diameter ≥2 cm) confirmed by pelvic ultrasound

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30 participants for each arm

Total final enrolment
120

Key exclusion criteria
1. Women who had used any steroid hormonal therapy for a minimum of 3 months prior
2. Lactating females
3. Menopausal women
4. Under the inclusion age limit
5. Menorrhagia

Date of first enrolment
15/02/2019

Date of final enrolment
30/12/2019

Locations

Countries of recruitment
Sri Lanka

Study participating centre
National Ayurveda Teaching Hospital
Cotta road, Borella, Sri Lanka
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Sponsor information

Organisation
University of Colombo

Sponsor details
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University/education

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ROR
https://ror.org/02phn5242

Funder(s)

Funder type
Government

Funder Name
University Grants Commission - Sri Lanka

Alternative Name(s)
UGC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sri Lanka

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal

Intention to publish date
30/03/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Kaumadi Karunagoda (kaumadik@gmail.com). Study participant data sheets will not include contact or identifying details. Study data entry and study management systems used by clinical sites will be secured and password protected. At the end of the study, all study databases will be de-identified and archived. Availability of raw data of the study is based on above conditions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2019	12/03/2019	Yes	No
Results article		28/06/2021	10/09/2021	Yes	No
Other publications	translation and validation of the Sinhala version of the UFS-QOL	25/09/2020	03/11/2021	Yes	No