ISSN 2456-3110
Vol 9 · Issue 6
June 2024

JAiMS
INTERNATIONAL

Journal of Ayurveda and Integrated Medical Sciences

www.jaims.in

JAIMS

An International Journal for Researches in Ayurveda and Allied Sciences

Maharshi Charaka
Ayurveda

Indexed

Journal of
Ayurveda and Integrated Medical Sciences
ISSN 2456-3110
ORIGINAL ARTICLE June 2024

A Prospective, Open-label, Non-randomised Clinical Trial to Evaluate the Safety and Efficacy of Femiforte in the Treatment of Leucorrhoea

Milind Patil[1], Nikhil Chaudhari[2], Damodar Dukle[3]

[1]Principal Investigator, [2,3]Co-Investigator, Dr. Dukle's Vedic Healing (Holistic Health), SDM Hospital, Plot No 80-A, Sector 19, Near Mother Teresa Garden, Nerul, Navi Mumbai, Maharashtra, India.

ABSTRACT

Objectives: To evaluate the clinical efficacy and safety of Femiforte Tablets in Leucorrhoea. **Materials and Methods:** A prospective, interventional clinical study was conducted on 40 female patients, aged between 24-49 years, confirmed with leucorrhoea from clinical examination and who were willing to give informed consent. All patients received Femiforte Tablet at a dose of 1 tablet twice a day for 4 weeks. All patients were evaluated at baseline and 4 weeks for parameters of malodor discharge, malodor discharge after intercourse, itching, dyspareunia, vaginal irritation, dysuria, lower abdominal pain; abnormal pH, bacterial vaginosis, trichomonas vaginitis and candidiasis; physician's and patient's global assessment at end of the study. **Observation and Results:** Femiforte Tablets reduced malodor discharge and malodor discharge after intercourse in 45% and 42.5% patients respectively, at the end of 4th week from baseline. At the end of 4th week, itching, dyspareunia and vaginal irritation had a reduction in 50%, 37.5% and 35% patients respectively, from baseline. At the end of 4th week, dysuria and lower abdominal pain had a reduction in 15% and 30% patients respectively, from baseline. **Conclusion:** Femiforte Tablets produced a significant reduction in all the parameters associated with leucorrhoea, assessed after 4 weeks of treatment. In addition, a significant improvement in clinical global impression in efficacy and tolerability was also observed. No adverse events were reported by any patients. This indicates that Femiforte Tablet is clinically effective and safe in leucorrhoea.

Key words: *Femiforte Tablet, Leucorrhoea, Curdy white discharge, Ayurveda*

INTRODUCTION

Leucorrhoea is also known as fluor albus i.e. body discharge that is excessively secreted from the genital organs. Such discharges may originate from the vagina, ovaries, fallopian tubes or most commonly from the cervix. In women, it may be physiological or pathological. Physiological leucorrhoea occurs due to the menstruation process. It is usually transparent to whitish coloured, and odourless; occurring within several months to a year of the onset of menses in adolescent girls and is sometimes present in newborn girls, usually lasting one to two months. It may also occur during pregnancy and is considered normal when the discharge is thin, white, and relatively odourless. On the other hand, pathological leucorrhoea is usually yellowish/greenish/greyish, smells offensive, fishy or foul, in large amount and causes complaints such as itching, redness (erythema), edema or tissue inflammation, burning sensation in the genitals, pain during sexual intercourse (dyspareunia) and urination (dysuria). The symptom of excessive discharge is a subjective one with individual variation, while to declare it to be normal and not an infective one, requires clinical and laboratory investigations.[1]

Pathological leucorrhoea may be caused by infections with bacteria, yeast, or other micro-organisms. For example, many sexually transmitted diseases, which

Address for correspondence:
Dr. Nikhil Chaudhari
Co-Investigator, Dr. Dukle's Vedic Healing (Holistic Health), SDM Hospital, Plot No 80-A, Sector 19, Near Mother Teresa Garden, Nerul, Navi Mumbai, Maharashtra, India.
E-mail: regulatory@charak.com

Submission Date: 02/04/2024 Accepted Date: 16/05/2024

Access this article online

Quick Response Code

Website: www.jaims.in

DOI: 10.21760/jaims.9.6.5

ISSN: 2456-3110 ORIGINAL ARTICLE June 2024

involve the transmission of viruses or bacteria and include diseases such as gonorrhoea and chlamydia, are major causes of leucorrhoea. These diseases lead to infection of the cervix, which is indeed one of the most common gynecological disorders. The infection has a tendency to irritate the mucus glands of the cervix, causing them to secrete an excess of mucous mixed with pus. Leucorrhoea is also a sign of vaginitis (inflammation of the vagina), which is often caused by infection with the fungus Candida albicans or by infection with the protozoan parasite Trichomonas vaginalis. Infection with these organisms may give rise to an irritating discharge that is often quite resistant to treatment. A tampon, diaphragm, or other foreign object left too long in the vagina can also cause Leucorrhoea.[2]

Epidemiology

Pathological leucorrhoea becomes the most common etiology in reproductive aged women and urethral discharge is the most complained symptom consulted to a gynaecologist. The highest incidence is found in the 21-30 years old age group. Pathological leucorrhoea indicates vaginitis or cervicitis. Three most common vaginal infections in pathological leucorrhoea includes bacterial vaginosis (BV), vulvo-vaginal candidiasis (VVC) and trichomoniasis, whereas cervical infection includes gonorrhea and chlamydiosis. Clinical manifestations of leucorrhoea and urethral discharge does not lead to mortality. However, it causes increased morbidity due to irritation and itch that leads to discomfort in sexual activity.[3] In a 2017 study, BV was reported as the most common pathological cause (27%), followed by trichomoniasis (25%), VVC (22%), co-infection (Candida and BV) (3%), and non-specific infection (23%).[4]

Pathogenesis & Clinical Presentation

Diagnosis is made through obtaining patient's history and laboratory exams. The treatment is given in accordance with the causative pathogens. Untreated physiological leucorrhoea may progress to pathological leucorrhoea with the risk of infertility.[5]

There are several factors affecting physiological leucorrhoea namely, age (pre-pubertal, reproductive, post-menopausal), hormones (hormonal contraception, hormonal cycle changes, pregnancy), and local factors such as menstruation, post-partum, malignancy, semen, and personal hygiene habits. Whereas pathological leucorrhoea is commonly caused by cervical and vaginal abnormality that can be non-infectious or infectious that cause vaginal discharge to change or become unpleasant smelling. Many of these infections can be caused by having sex with someone who has the infection.

Patients with leucorrhoea usually complain smelly vaginal discharge with vaginal itching. The clinical manifestations of leucorrhoea differ based on the causative agent. The discharge is usually a thin liquid but sometimes may be thick and sticky. The color of pathological leucorrhoea may be whitish, greyish-white, yellowish, greenish, reddish, dark colored or rustic; accompanied with other symptoms such as excessive amount of discharge, itching and burning. Other clinical manifestations of vaginal leucorrhoea include thigh and leg muscle pain, burning sensation when urinating, foul odor, itching or pain in the infected area, anorexia, constipation, and fatigue. Cervical leucorrhoea is usually accompanied with low back pain.

Non-infection: Non-infection disorders that cause vaginitis include foreign bodies, vulvar vestibulitis, and allergic vaginitis. A foreign object in the vagina causes inflammation, which results in an unpleasant odor and excess exudate. The most common foreign bodies that cause vaginitis are toilet paper and tampons. Genital hygiene and contraceptive products are the most common etiologies of non-infectious vaginitis that cause allergic contact dermatitis and irritant contact dermatitis. Meanwhile, non-infectious cervical disorders include cervical ectopy, chronic cervicitis, mucous polyps, and ectropion.

Infection: Neiserria gonorrhoeae and C. trachomatis are the most common causes of cervical infections (cervicitis). Cervicitis is often asymptomatic, but in some women it is accompanied by complaints of vaginal discharge and intermenstrual vaginal bleeding (after sexual intercourse). Bacterial vaginosis, VVC, and

ISSN: 2456-3110 ORIGINAL ARTICLE June 2024

trichomoniasis are the most common conditions causing vaginal infections (vaginitis).

Diagnosis:

Vulvovaginitis symptoms can be diagnosed through basic diagnostic procedure such as medical history, physical examination and other supportive examination which includes vaginal pH examination, whiff/KOH test, and microscopic wet preparation test. Microbiologic examination is also performed if there is a recurrent or chronic persistent infection.

Conventional Treatment

Advances in the understanding of leucorrhoea or vaginal discharge and its pathophysiology have led to development of highly effective and targeted treatments. However, treating vaginal discharge will depend on the causative factors. Douching is not recommended, since this practice often disturbs the balance of normal vaginal flora, thereby exacerbating infection. Treatment is aimed at eliminating the underlying cause and typically involves administration of an anti-microbial agent. Abnormal vaginal discharge caused by a yeast infection is usually treated with anti-fungal medications. These come as pills, as well as creams or gels that can be inserted directly into the vagina. If the discharge is caused by bacterial vaginosis, it can be treated with antibiotics or creams. Trich infections are treated by metronidazole or tinidazole.

Antibiotics can effectively clear up the infection but they may also have some side-effects. Antibiotics can disrupt the balance of bacteria and yeast in the vagina, leading to an overgrowth of yeast and causing a yeast infection. This can result in symptoms such as itching, burning, and abnormal vaginal discharge. Also, they can affect the natural balance of bacteria in the digestive system, leading to gastro-intestinal side-effects such as diarrhea, nausea, vomiting, or abdominal pain. Overuse or misuse of antibiotics can contribute to the development of antibiotic-resistant bacteria, making future infections more difficult to treat. Antibiotics not only kill harmful bacteria but can also disrupt the balance of beneficial bacteria in the body, potentially leading to complications such as secondary infections or prolonged disruption of the vaginal microbiome.

Patients with leucorrhoea do not have access to a remedy that cures the condition or stops the recurrence. Current therapeutics possess certain drawbacks, including the frustration of the patients due to the ineffectiveness of drugs and possible side-effects such as drug resistance, diarrhea, and vomiting. There is a lack of an effective and long-term treatment plan in the fight against leucorrhoea. There is a great need for the continuous development of new, safe, and effective treatment of leucorrhoea. Among the many active compounds that have been studied for the relief of leucorrhoea, extracts from plants and specific phyto-chemicals from natural resources have been of great interest in recent decades. Several studies evaluating leucorrhoea therapy based on natural sources revealed potential activity, especially in reduction of vaginal discharge, itching, and lowering the levels of inflammation cytokines. Natural substances, in comparison with medicament, do not cause such adverse effects, which is the positive side of their use.

In the present study, Femiforte Tablet, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patients with leucorrhoea.

Objectives of the Study

The main objective of the study was to evaluate the clinical efficacy of Femiforte Tablet in Leucorrhoea. Further, the study also observed the clinical safety of Femiforte Tablet in Leucorrhoea.

Materials and Methods

Study Design

A non-randomized phase 4, prospective open label clinical trial in 40 patients diagnosed with leucorrhoea was planned following required GCP guidelines. After careful selection in terms of the eligibility criteria, screened subjects willing to enrol after explaining the clinical study procedure were requested to sign the Patient Consent Form. At baseline visit (0 weeks), Patient information sheet was provided to each subject in their language of preference. Case record form (CRF)

ISSN: 2456-3110 ORIGINAL ARTICLE June 2024

was filled by the attending physician with complete medical history and required personal details of the subject at the start of the study. A thorough physical examination and necessary laboratory investigations were carried out before drug administration and after completion of treatment.

Safety and efficacy evaluation of patients' clinical response to treatment was monitored from baseline till end of 4 weeks. All data were carefully entered in the Case Record Form provided. Side-effects were closely monitored in all patients. All adverse events were recorded by the investigator, and rated for severity and relationship to the study medication.

Inclusion Criteria

Females, aged 24 to 49 years and visiting the outpatient department, experiencing symptoms of leucorrhoea, such as abnormal vaginal discharge (quantity, color, consistency), associated itching, burning sensation, or foul odor. Patients willing to provide informed consent; comply with study requirements, attending study visits and adhering to treatment protocols; having adequate understanding of the study procedures and ability to communicate effectively with study staff; to be available for the duration of the study period were enrolled in the study.

Exclusion Criteria

Pregnant females, as pregnancy can alter vaginal discharge patterns and may require different management approaches. Post-menopausal females, as vaginal discharge patterns and causes differ significantly from those in pre-menopausal women. Individuals who have recently taken antibiotics, as this can affect vaginal flora and discharge characteristics. Individuals with chronic conditions that may affect vaginal health or immune function, such as diabetes mellitus or autoimmune diseases. Individuals undergoing hormonal therapy or treatment that may influence vaginal discharge patterns. Individuals who have undergone hysterectomy (surgical removal of the uterus), as this can impact vaginal discharge. Individuals with known gynecological conditions that may mimic or complicate the diagnosis of leucorrhoea, such as cervical or endometrial cancer. Patients with any other condition or circumstance that, in the judgment of the investigator, would make the participant unsuitable for participation in the study were excluded. Patients suffering from malignancies, cardiovascular, respiratory, kidney diseases, with serious medical conditions that could confound study outcomes or increase the risk of complications during the study period, who are unable or unwilling to provide informed consent or comply with study procedures and follow-up assessments were excluded.

Patients could be withdrawn from the study at their own request or if they experience intolerable adverse events, show insufficient therapeutic effect, or needed deviations from the protocol at the discretion of the investigator.

Clinical assessments

The patients were evaluated at baseline and 4 weeks after onset of treatment. Efficacy was evaluated on the basis of malodor discharge, malodor discharge after intercourse, itching, dyspareunia, vaginal irritation, dysuria and lower abdominal pain. Vaginal smear was done before and after treatment to detect abnormal pH, presence of clue cells, candida albicans, gardnella and trichomonas to diagnose bacterial vaginosis, trichomonas vaginitis and candidiasis. Whiff test was also performed to assess amine odor of discharge. Vaginal discharge in BV & TV patients was assessed on a scale of 0-3, namely 0 = no discharge, 1 = mild; 2= moderate and 3 = severe. The Physician global assessment and Patient's global assessment (at end of the study) on efficacy and tolerability were made on a scale of 1- 5, namely, Very Good = 5, Good = 4, Fair = 3, Poor = 2 and Very Poor = 1.

Intervention

Femiforte Tablet, manufactured by Charak Pharma Pvt. Ltd. was studied for its efficacy and safety in patients with leucorrhoea, in a dose of 1 tablet twice a day for 4 weeks. Femiforte Tablet contains *Saraca indica, Curcuma longa, Symplocos racemosa, Asparagus racemosus, Amaranthus spinosus, Berberis aristata, Cedrus deodara, Emblica officinalis* and *Tinospora cordifolia.*

ISSN: 2456-3110 ORIGINAL ARTICLE June 2024

OBSERVATION

All 40 patients enrolled in the trial completed the study with reduction in symptoms of leucorrhoea to varying degrees. Table 1 shows Demographic data of Patients who participated in our study before intervention. Treatment with the Femiforte tablet did not lead to any abnormalities in the laboratory investigations as compared to the baseline values. Patients tolerated the trial medications without any adverse events that needed discontinuation. Table 2 shows signs and symptoms of vaginitis i.e., malodor, malodor discharge after intercourse, itching, dyspareunia, vaginal irritation, dysuria and lower abdominal pain. After 4 weeks of treatment with Femiforte Tablets, there was a reduction in the number of patients who suffered from malodor, malodor after intercourse, vaginal irritation, dyspareunia and lower abdominal pain. Table 3 shows changes in laboratory diagnosis of patients with vaginitis before and after treatment. Laboratory findings of the patients with vaginitis are presented in Table 4 and 5. Laboratory findings included vaginal pH, Whiff test and presence of Clue cells, Candida albicans, Gardnerella and Trichomonas. Table 5 also shows the reducing trends in discharge of BV and TV patients. Table 6 and 7 shows Global assessment of response by Physicians and Patients respectively after 4 weeks of treatment.

Table 1: Demographic Data of Patients at Baseline

Variables	Mean ± S.D.
Age (years)	39.40 ± 10.68
Age at marriage (years)	19.55 ± 4.30
BMI (kg/m^2)	25.83 ± 3.72
Husband age (years)	43.73 ± 10.31
Number of intercourse per week	1.47 ± 1.21
Number of pregnancy	2.70 ± 1.59
Number of childbirth	2.20 ± 1.44
Number of cesarean section	0.50 ± 0.82
Number of abortion	0.48 ± 0.68
Number of living children	2.25 ± 1.39
Duration of menstrual bleeding (days)	6.57 ± 2.34

Table 2: Changes in the mean symptom scores after 4 weeks of therapy

Parameters	Baseline	After 4 Weeks
Malodor discharge	26 (65.0%)	8 (20.0%)
Malodor discharge after intercourse	17 (42.5%)	0 (0.0%)
Itching	25 (62.5%)	5 (12.5%)
Dyspareunia	20 (50.0%)	5 (12.5%)
Vaginal irritation	20 (50.0%)	6 (15.0%)
Dysuria	11 (27.5%)	5 (12.5%)
Lower abdominal pain	23 (57.5%)	11 (27.5%)

Table 3: Changes in Laboratory Diagnosis of Vaginitis after 4 weeks of therapy

Parameters	Baseline	After 4 Weeks	p Value
Bacterial vaginosis (BV)	11 (27.50%)	9 (22.50%)	0.581
Trichomonas vaginitis (TV)	32 (80.00%)	6 (15.00%)	0.000
Mixed	3 (17.6%)	1 (2.50%)	0.625
Fungi	5 (12.50%)	4 (10.00%)	1.000
Total Cured	26 (65.00%)		

Table 4: Changes in Laboratory finding of Vaginitis after 4 weeks of therapy

Parameters	Baseline	After 4 Weeks	p Value
Abnormal pH (>4.5)	40 (100.0%)	14 (35.0%)	0.000
Whiff test (Positive)	29 (72.5%)	2 (5.0%)	0.000

ISSN: 2456-3110 ORIGINAL ARTICLE June 2024

Clue cells (Presence)	7 (17.5%)	4 (10.0%)	0.508
Candida albicans (Presence)	5 (12.5%)	4 (10.0%)	1.000
Gardnerella (Presence)	6 (15.0%)	4 (10.0%)	0.727
Trichomonas (Presence)	2 (5.0%)	1 (2.5%)	1.000

Table 5: Trend in Discharge

Parameters	Baseline (mean ± S.D.)	After 4 Weeks (mean ± S.D.)	Difference (mean ± S.D.)
Discharge in BV Patients	2.18 ± 1.08	0.64 ± 0.50	−1.55 ± 1.21
Discharge in TV Patients	2.16 ± 1.019	0.97 ± 0.740	−1.19 ± 0.965

Table 6: Global assessment of response by Physicians after 4 weeks of treatment.

Assessment by Physicians	Very Poor	Poor	Fair	Good	Very Good
Efficacy	0	0	8	26	6
Tolerability	0	0	5	31	4

Table 7: Global assessment of response by Patients after 4 weeks of treatment.

Assessment by Physicians	Very Poor	Poor	Fair	Good	Very Good
Efficacy	1	4	14	24	0
Tolerability	0	2	4	32	2

RESULTS

Femiforte Tablets could eliminate malodor discharge and were effective in improving malodor discharges after intercourse and relieving irritation. At the end of 4th week, malodor discharge and malodor discharge after intercourse had a reduction in 45% and 42.5% patients respectively, from baseline. At the end of 4th week, itching, dyspareunia and vaginal irritation had a reduction in 50%, 37.5% and 35 % patients respectively, from baseline. At the end of 4th week, dysuria and lower abdominal pain had a reduction in 15% and 30% patients respectively, from baseline. Femiforte Tablets reduced the incidence of abnormal pH, bacterial vaginosis, trichomonas vaginitis and candidiasis with a overall cure rate of 65%. Further, Femiforte Tablets were helpful in treating discharge in both BV and TV patients. The global assessment of response by patients showed that 60% of patients showed a good improvement while another 35% showed fair improvement in their condition by the end of 4 weeks of treatment. Similarly, 65% and 20% of the physician's global assessment indicated good and fair response at the end of treatment respectively. These findings confirm the efficacy of Femiforte Tablets in the study population during the study period.

DISCUSSION

Leucorrhoea is a condition of persistent and excessive vaginal discharge. It is one of the most common chief complains in clinical medicine. The term leucorrhoea is applied to cases of abnormal vaginal discharge, non-haemorrhagic in nature, which is not caused by neoplasm or other serious disease. Leucorrhoea could be physiological when associated with various phases of menstrual cycle or due to cervical/vaginal inflammation or diseases. It can be due to infection with Trichomonas vaginalis, Candida albicans or mixed bacterial infections, chronic cervicitis or malignancy. It is also difficult condition to treat satisfactorily in view of its uncertain etiologic. The etiology of leucorrhoea is complex and not well understood. It is considered that changes in the vaginal epithelium; changes in the normal bacterial flora and pH of the vaginal secretion predispose to leucorrhoea.[6]

Genital tract infections form one of the major burdens of disease in developing countries, and includes infections caused due to any or combination of the three factors: iatrogenic, endogenous, and sexually transmitted. While there are several symptoms that define the disease, the most commonly reported among the women is that of Leucorrhoea.[7] The impact

ISSN: 2456-3110 ORIGINAL ARTICLE June 2024

that arises from vaginal discharge is discomfort in women and a serious consequence is infertility.[8]

Advances in the understanding of leucorrhoea or vaginal discharge and its pathophysiology have led to development of highly effective and targeted treatments depending on the causative factors. Treatment typically involves administration of an anti-microbial agent which can effectively clear up the infection but may also have some side-effects. Antibiotics not only kill harmful bacteria but can also disrupt the balance of beneficial bacteria in the body, potentially leading to complications such as secondary infections or prolonged disruption of the microbiome. Overuse or misuse of antibiotics can contribute to the development of antibiotic-resistant bacteria, making future infections more difficult to treat. There is a lack of an effective and long-term treatment plan in the fight against leucorrhoea. Several studies evaluating leucorrhoea therapy, based on natural sources have revealed potential activity, especially in reduction of vaginal discharge, itching, and lowering the levels of inflammatory cytokines. Natural substances, in comparison with medicament, do not cause such adverse effects, which is the positive side of their use.

Research reveals that one of the possible ways to break the pathophysiology in leucorrhoea course is to use herbal drugs and exploit their immunoregulatory, anti-inflammatory, anti-microbial and antioxidative role in the treatment.[9,10] Literature reviews document the usefulness of herbal remedies for leucorrhoea and the supportive role of phytochemicals in this disease treatment.[11]

Saraca asoca contains flavonoids, tannins, steroids, volatile oil, glycosides, steroidal glycosides, and polyphenols. It is known to have properties like anti-inflammatory, antioxidant, alexiteric, anti-bacterial, anti-pyretic and analgesic activities useful in the treatment of leucorrhoea.[12] *Curcuma longa* contains phenolic compounds useful as an antioxidant, analgesic, anti-microbial, anti-inflammatory.[13] *Symplocos racemosa* is an important Indian traditional drug used in many Ayurvedic and herbal formulations for treatment of uterine disorders and leucorrhoea. Majority of phyto-pharmacological reports are of stem bark of the plant, including anti-cancer, antioxidant, anti-androgenic, anti-inflammatory, wound healing and anti-diabetic effects. Phyto-chemical studies indicated presence of many phenolic glycosides like symplocoside; triterpenoids like betulinic acid, acetyloleanolic acid and oleanolic acid; flavonoids like quercetin which contribute to the observed protective effects.[14]

CONCLUSION

The present interventional study indicates that Femiforte Tablets are effective and safe in controlling the signs and symptoms of leucorrhoea and its associated complications. There were no clinically significant adverse events either reported or observed during the entire study period. The overall compliance with the treatment was good and no treatment discontinuations were reported. Femiforte Tablets typically target microbial growth, inflammatory mechanisms and free radicals. Femiforte aims at reverting pathogenic leucorrhoea with an alternative approach to disconnect the causative factors from inflammation and to reduce malodor discharge, itching, dyspareunia, vaginal irritation, dysuria and lower abdominal pain.

Cost of Study

All medications required during the 4 weeks of trial were provided by the sponsor. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

Conflict of Interest

To avoid any conflict of interest, study was carried out under the unbiased supervision of Dr. Dukle's Vedic Healing HCP who are not associated with the sponsors.

REFERENCES

1. Konar H. Leucorrhea. In: Dutta DC, editor. Textbook of Gynecology. 6th ed. Philadephia: Jaypee Brothers Medical Publishers; 2013. p. 551-579.
2. Rao VL, Mahmood, T. Vaginal discharge. Obst Gyn Reproduct Med. 2019; 30(1): 11–18.

ISSN: 2456-3110 **ORIGINAL ARTICLE** June 2024

3. Bai R, Deepthi M, MN D. Analysis of leucorrhoea in tertiary care hospital in rural Bangalore. IJCOG 2018; 2(4): 76–79.
4. Venugopal S, Gopalan K, Devi A. Epidemiology and clinico-investigative study of organisms causing vaginal discharge. Indian J Sex Transm Dis AIDS 2017; 38(1): 69-75.
5. Hainer BL, Gibson MV. Vaginitis: diagnosis and treatment. Am Fam Physician 2011; 83(7): 807-815.
6. Abid, Maham & Jyoti, & Kumar, Kapil & khan, Roomi & Ali, Salman & Chandra, Phool & Rani, Renu & Ali Khan, Najam. (2016). Assessment of Leucorrhea diseases in female students. Journal of Scientific and Innovative Research. 5. 116-118. 10.31254/jsir.2016.5402.
7. Joshi A, Dhapola M.& Pelto P. (2008):Gynecological Problems: Perceptions and Treatment-seeking Behaviors' of Rural Gujarati Women. In: Michael A Koenig, ShireenJejeebhoy, John C Cleland, BelaGanatra., editors. Reproductive Health journal.in India New Evidence. Jaipur: Rawat Publications;.133–583.
8. Ayu Wantini, Nonik. (2021). Improvement of Reproductive Health Knowledge (Vaginal Discharge and Menstrual Pain) in Women. Jurnal Ners dan Kebidanan (Journal of Ners and Midwifery). 8. 055-063. 10.26699/jnk.v8i1.ART.p055-063.
9. Dehdari S, Hajimehdipoor H. Herbal Medicines for Leucorrhea According to Iranian Traditional Medicine. Iran J Med Sci. 2016 May;41(3 Suppl):S36. PMID: 27840502; PMCID: PMC5103543.
10. Dulal Chandra Das, Nirmalya Kumar Sinha, Malay Kumar Patsa, Monalisa Das. Investigation of Herbals for the Treatment of Leucorrhoea from South West Bengal, India. International Journal of Bioassays 4.11 (2015): 4555-4559.
11. COULD HERBAL MEDICINE BE A COMPLEMENTARY THERAPY IN LEUCORRHEA TREATMENT AND CARE?. (2019). *Proceedings of the International Conference on Applied Science and Health*, *4*, 621-627.
12. Kumari I, Madhusudan S, Kaurav H and Chaudhary G: Phytomedicinal value of Saraca asoca (ashoka) in enhancing female reproductive systemin ayurveda and folk system of medicine. Int J Pharmacognosy 2021; 8(6): 193-03. doi link: http://dx.doi.org/10.13040/IJPSR.0975-8232.IJP.8(6).193-03.
13. Ayu Wantini, Nonik. (2021). Improvement of Reproductive Health Knowledge (Vaginal Discharge and Menstrual Pain) in Women. Jurnal Ners dan Kebidanan (Journal of Ners and Midwifery). 8. 055-063. 10.26699/jnk.v8i1.ART.p055-063.
14. Niyati Acharya, Sanjeev Acharya, Unnati Shah, Ripal Shah, Lal Hingorani, A comprehensive analysis on Symplocos racemosa Roxb.: Traditional uses, botany, phytochemistry and pharmacological activities, Journal of Ethnopharmacology, Volume 181, 2016, Pages 236-251

How to cite this article: Milind Patil, Nikhil Chaudhari, Damodar Dukle. A Prospective, Open-label, Non-randomised Clinical Trial to Evaluate the Safety and Efficacy of Femiforte in the Treatment of Leucorrhoea. J Ayurveda Integr Med Sci 2024;6:29-36. http://dx.doi.org/10.21760/jaims.9.6.5

Source of Support: Nil, **Conflict of Interest:** None declared.

****