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# GYNAE SPECTRUM

Dear Doctor,

Greetings from Micro Labs. We are happy to bring you "**Gynae Spectrum**", which contains latest and interesting news in the field of Obstetrics and Gynaecology.

This issue contains:

- **L. Crispatus CTV-05 strain vs Placebo in bacterial vaginosis.**
- **Caesarean Scar Hidradenitis Suppurativa - A case report.**
- **A Remote Pregnancy Monitoring System**

Should you require any article or, medical information, please feel free to contact us  
[medicalservices@microlabs.in](mailto:medicalservices@microlabs.in)

Looking forward to your valuable feedback.

Best Regards,

Medical Team, Micro Labs Limited

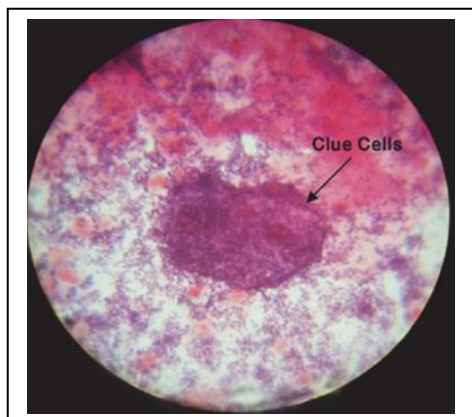
## 1. *L. Crispatus* CTV-05 strain vs Placebo in bacterial vaginosis.

Bacterial vaginosis (BV) is an imbalance of the vaginal microbiota affecting mostly women of reproductive age group. Overall prevalence in India is 24.4% among symptomatic patients.

Lactobacilli produce antimicrobial substances like lactic acid, H<sub>2</sub>O<sub>2</sub>, and bacteriocin to promote a healthy ecosystem in the vagina thereby suppressing the growth of pathogens.

*Lactobacillus crispatus* is a live biotherapeutic product that has naturally occurring vaginal strain of *L. crispatus*.

It is present in powder form containing  $2 \times 10^9$  colony-forming units (CFU) of *L. crispatus* preserved with inactive ingredients and is administered with the use of a prefilled vaginal applicator.



Current study is a phase 2b trial designed to assess treatment with *L. crispatus* CTV-05 strain after a 5-day course of metronidazole to treat bacterial vaginosis would be compared to placebo.

### Methods:

A randomized, phase 2b trial, double-blind study, placebo-controlled study.

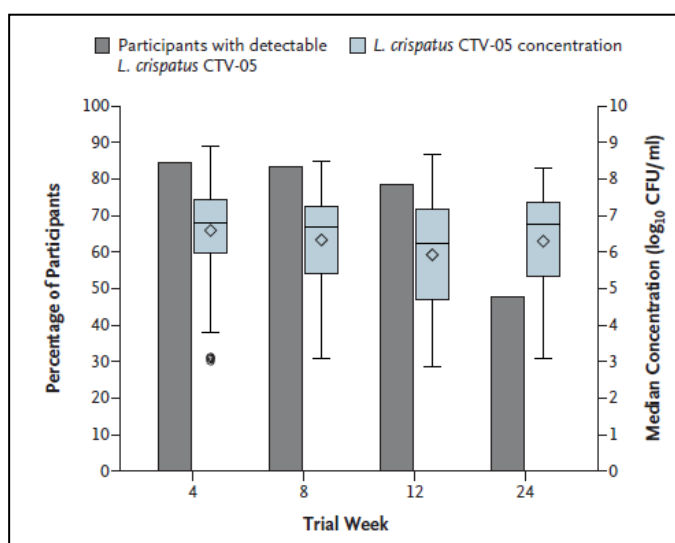
300 Women with 18 to 45 years of age diagnosed with bacterial vaginosis and completed a course of vaginal metronidazole gel were included in the study.

Patients were randomly assigned in a 2:1 ratio, 200 patients received vaginally administered *Lactobacillus crispatus* CTV-05 strain or 100 patients received placebo for 11 weeks; follow-up occurred on 12 weeks, 24 weeks.

Primary outcomes were assessed based on percentage of women who had recurrence of bacterial vaginosis by week 12 weeks.

**Results:** Bacterial vaginosis recurrence occurred by week 12, in 12% of participants with *Lactobacillus crispatus* CTV-05 strain group compared to (17%) in the placebo.

The risk ratio for recurrence by week 24



was 0.73 In the *L. crispatus* CTV-05 strain group and was detected in 79% (at week 12) to 84% of participants during weeks 4, 8, and 12 and in 48% of participants at week 24 .

No apparent associations existed between the detection of *L. crispatus* CTV-05 at week 12 or week 24 and adherence to the assigned treatment, occurrence of menses since the last visit, or occurrence of sex without the use of a condom.

**Safety :** Most common local adverse events were abnormal vaginal discharge, abnormal vaginal odor, external genital irritation, and genital itching.

#### Discussion:

Vaginal dysbiosis (also known as bacterial vaginosis) is characterized by displacement of optimal vaginal microflora by diverse bacteria, often recurs after therapy, and has been associated with multiple adverse health outcomes.

In current study, treatment with *L. crispatus* CTV-05 strain for bacterial vaginosis resulted in a significantly lower incidence of recurrence of bacterial vaginosis at 12 weeks than placebo, benefit appeared to persist throughout week 24.

Adherence to treatment was high.

#### Conclusion:

In bacterial vaginosis patients, use of Lactin-V after treatment with vaginal metronidazole resulted in a lower incidence of recurrence of bacterial vaginosis at 12 weeks than placebo.

#### Reference:

Cohen CR et al. Randomized trial of Lactin-V to prevent recurrence of bacterial vaginosis. N Engl J Med 2020 May 14; 382:1906.

## 2. Caesarean Scar Hidradenitis Suppurativa - A case report.

Hidradenitis suppurativa (HS) being a chronic, relapsing inflammatory skin condition characterised by the presence of painful nodules, abscesses, and sinus tracts or scarring.

It is seen predominantly in females at a ratio of 3 : 1. It is also associated with inflammatory bowel disease, depression and other psychiatric conditions, and the metabolic syndrome.

Here is a case presentation of Hidradenitis





Suppurativa with a recurrence in a caesarean scar.

#### Case presentation:

38 old female managed earlier HS successfully with adalimumab 40mg injections weekly. Patient became pregnant with her first child and continued adalimumab until the end of the second trimester.

A healthy 3.59 kg male baby was delivered via emergency caesarean section at 39 weeks. HS remained silent throughout the pregnancy and after the birth, one week later three painful nodules appeared in her left axilla.

Patient self-medicated adalimumab at this time, after ceasing breast feeding, these nodules settled. Approximately two months later, the appearance of small nodules and inflammatory tracts around caesarean scar started.

Initially thought as fungal infection and was treated with antifungal cream with limited efficacy. Patient was subsequently treated with topical antimicrobial preparation containing gramicidin, neomycin sulfate, nystatin, and triamcinolone acetonide, followed by oral amoxycillin and clavulanic acid, and potassium permanganate s but provided minimal improvement.

Patient reported in clinic one month after the onset of symptoms. Presence of a number of small, well-defined HS lesions, with nodules and discharging sinus tracts around the caesarean scar.

Disease remained silent, and her compliance with Adalimumab was excellent. She was subsequently diagnosed with a recurrence of HS in her caesarean scar, providing her with a sense of relief following the multiple previous presentations

Lesions of HS involving caesarean site responded well to treatment with doxycycline 100mg daily and polyhexanide Wound Gel and Wash (polyaminopropyl biguanide (polyhexanide), betaine surfactant) in addition to Adalimumab.

Discharging sinus tracts persisted until review six months after the onset of symptoms, and complete resolution occurred at one year.

#### Discussion:

Hidradenitis suppurativa is a chronic, disabling, suppurative disease characterized by deep tender subcutaneous nodules; complicated by fibrosis and extensive sinuses affecting primarily the apocrine gland bearing areas.

It causes tremendous psychological stress for those patients who suffer from it.

Pain and discharge from draining sinuses and abscesses significantly impair a patient's ability to work, exercise.

#### Conclusion:

A case of recurrent HS in a caesarean scar was successfully treated with Adalimumab.

#### Reference:

Darch KM et al. Hidradenitis Suppurativa Recurrence in a Caesarean Scar. Case Reports in

IN FOCUS

## A Remote Pregnancy Monitoring System



A company has received FDA clearance for a wearable device that remotely monitors fetal and maternal heart rates.

Fetal and maternal heart rates are important measurements late in pregnancy, and an elevated fetal heart rate is one of the signals of fetal distress.

Fetal heart monitoring usually requires regular visits to hospital or clinic. The device allows patients and physicians to monitor these data points remotely with convenience and accuracy.

The device is meant for use in the third trimester of pregnancy. Doctor will schedule remote monitoring sessions, during which the patient wears device sensor band to collect heart rate data.

Measurements are accessible through a smartphone app and are also uploaded doctor.

This is beneficial for pregnant women, a new and more convenient ways to connect with patients .



Reference:

Available at : <https://www.medgadget.com/2020/03/invu-receives-fda-clearance-for-remote-pregnancy-monitoring-system.html>. Accessed on 10-06-2020.



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