Coriolus versicolor for HPV Patients with Cervical Lesions (LSIL)[1,2]

Link between HPV and Cervical Cancer

Cervical cancer rates are high in women between the ages of 35 and 55. Risks increase with earlier sexual intercourse, number of sexual partners and failure to have regular Pap tests. Once diagnosed with HPV, there may a change in cervical epithelial cells from normal (CIN-0) to one of two squamous cell types: high-grade squamous intraepithelial lesions (HSIL) or low-grade squamous intraepithelial lesions (LSIL).

CIN Status	Epithelial Status	Category
CIN-0		Normal
CIN-1	LSIL	Minimal or mild cervical dysplasia
CIN-2	HSIL	Moderate cervical dysplasia
CIN-3	HSIL	Severe cervical dysplasia
CIS	HSIL	Carcinoma *in situ*
	HSIL	Invasive Carcinoma

CIN-2/ CIN-3 Treatment (HSIL)

Treatment for HSIL involves removing lesions with scalpel, laser therapy, or loop electrosurgical excision. For more advanced cancer (CIS), radical hysterectomy is usually necessary. Radiation therapy is also highly effective for treating advanced cervical cancer that has not spread beyond the pelvic region.

CIN-1 Treatment (LSIL)

The usual treatment for CIN-1 patients is one of "wait and see". In women (and their sexual partners) over the age of 35, especially those who take oral contraceptives and smoke, their immune system is often too compromised to clear the virus. Consequently, when diagnosed with CIN-1 (LSIL-HPV) infection, such patients may need adjunct supplementation to support their immune system against progressive HPV infection.

Study Design and Protocol

The year-long study, funded by Mycology Research Laboratories Ltd. included forty-three (43) patients with HPV Lesions (LSIL) who were divided into two groups:

1. Control Group (21) did not receive any treatment;
2. The second group (22) received *Coriolus versicolor* supplementation for a period of one year (6 tablets/day i.e. 3g/day).

The patients were examined with colposcopy, biopsy and HPV tipification (hybrid capture) at the first observation. Cervical cytology exams (Pap smear tests) determined the patients' LSIL status, confirmed through colposcopy and biopsy. Four months later, colposcopy and cervical cytology were repeated on all patients, and an evaluation performed of the possible side effects from Coriolus supplementation.

After one year, all patients were examined for the third time (colposcopy, cervical cytology and HPV tipification).

Parameters of Outcome Measures

The efficacy of Coriolus supplementation in LSIL patients was evaluated in terms of the evolution of HPV tipification from High Risk HPV+ to High Risk HPV- status as well as persistence of cervical lesions measured by colposcopy and cytology.

Study Population

Of the 43 patients who started the trial, 39 completed it. Of the four (4) who did not complete the trial, 1 patient left the country and 3 discontinued supplementation due to mild side-effects.

The age distribution of the two groups was similar; patients receiving *Coriolus versicolor* supplementation had an average age of 31.7 years; the control group had an average age of 33.4 years.

Results

Of the 39 patients who completed one year of follow-up 18 took Coriolus supplementation, while the other 21 patients received no therapy (Control group). After 1 year, 13 of the 18 patients in the Coriolus group showed normal cervical cytology (72.5%); 10 of the patients in the control group did (47.5%).

Of the 39 patients, 22 were positive for high risk HPV subtypes. 10 of these patients were in the Coriolus group and 12 in the control group. After 1 year, 9 of the 10 in the Coriolus group had reverted to HPV- status (90%); 1 of the 12 in the control group had (8.5%).

The results indicated that *Coriolus versicolor* supplementation over a period of one year significantly increased regression of the dysplasia (LSIL) and clearance of the high risk sub-types of the HPV virus responsible for cervical cancer.

a. *Coriolus versicolor* supplementation demonstrated a 72% regression rate in LSIL lesions compared to 47.5% without supplementation;
b. *Coriolus versicolor* supplementation demonstrated a 90% regression rate in the high risk HPV virus sub-types compared to 8.5% without supplementation.

Discussion and Conclusion

While the study sample is limited in number, the results suggested that *Coriolus versicolor* supplementation offers gynaecologists a useful nutritional tool when treating HPV (LSIL) patients.

Coriolus versicolor could also be beneficial in HSIL patients who have undergone surgery but who experience recurrent lesions in order to reduce the viral load.

References and Notes

1. J Silva Couto and D Pereira da Silva. *Evaluation of the Efficacy of Coriolus Versicolor Supplementation in HPV Lesions (LSIL)*. Presented at the 20th European Congress of Obstetrics and Gynaecology Lisbon Congress Centre. March 4-8 2008.
2. The *Coriolus versicolor* was supplied by Mycology Research Laboratories Ltd.

Further Information

For further clinical information please contact Dr Jean Monro of Breakspear Hospital on info@breakspearmedical.com For information regarding the *Coriolus versicolor* used in this study please contact Vivian Wang on info@mycologyresearch.com