

Cranberry supplements as prophylactic treatment

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Phase VI: Evaluation The primary anticipated outcome that is expected with the prophylactic use of cranberry supplements would be the reduction in the incidence of recurrent urinary tract infection in women, in the age group of 18 to 65 years. The presence or absence of urinary tract infection would be confirmed by the visiting consultant physician. The secondary outcomes that will be noted are the frequency of urination (polyuria), hematuria and the status of antibiotics administration. Apart from that the diagnosis of an infection will be correlated by total WBC count and counts of C - reactive protein (Lane and Takhar, 2011).

From the above parameters it may be anticipated that if cranberry supplements are really useful then the frequency of urinary tract infection will decrease, the symptoms of UTI like polyuria and hematuria will decrease, the diagnostic results will show normal count (5000-9000 cu mm) of WBC and reduced levels of C - reactive protein. The further anticipated outcome will be the reduction in the frequency of antibiotics prescribed or there will also be a reduced need to escalate the dosage and class of an antibiotic. This means that though infection may occur but it does not require the intervention with an antibiotic and the innate immunity of the body can take care of the situation. Further decreased need to escalate the dosage and class of an antibiotic also implicate that chances of antibiotic resistance would not be high, if cranberry supplements are administered (Lane and Takhar, 2011) (Wang, Fang and Chen, 2012)

The protocol will be evaluated with the help of statistical tests of significance and in this regard the “ chi square test” will be performed. First of all stratified random sampling would be done to specify the sample sizes and

the limits. Seven groups will be formed with the women in the age range of 18 to 67 years. These groups are 18-28 years, 29-38 years, 39–48 years, 49-58 years, 59-68 year, 69-78 years and 79-88 years. Data will be collected from the urologists who classify that these women are patients of recurrent urinary tract infections. Patients below and above the specified age range will not be included in the study. Further newly diagnosed patients of UTI will also be not included in the study.

After selection of samples the patients in each group will be separated as the experimental arm and control arm. The patients of the experimental arm will only be administered cranberry supplements and the patients of control arm will receive placebo treatment. However as the study will be a single blind randomized trial only the investigator will be aware as to which are the patients that are treated with cranberry supplements and which are the patients that are treated with placebo.

The hypothesis will be tested on the basis of the chi square value. If the chi square value is > 0.05 then it will indicate that cranberry supplements have not reduced the recurrence of UTI, have not reduced the symptoms of UTI like polyuria or hematuria, and have not reduced the counts of WBC or the incidence of frequency of antibiotic usage. This means any change in both the groups have occurred due to chance factors of random sampling and it may be concluded that the cranberry supplements are not effective prophylactic agents in reducing the incidences of recurrent UTI in the specific age group/s of women those who were included in the study (Greenwood and Nikulin, 1996).

However if the chi square value is < 0.05 then it will indicate that cranberry

supplements have significantly reduced the recurrence of UTI, reduced the symptoms of UTI like polyuria or hematuria, and have reduced the counts of WBC or the incidence of frequency of antibiotic usage. This means any change in both the groups have not occurred due to chance factors of random sampling and it may be concluded that the cranberry supplements are effective prophylactic agents in reducing the incidences and symptoms of recurrent UTI in the specific age group/s of women those who were included in the study (Greenwood and Nikulin, 1996).

As mentioned the various variables that are included in the evaluation of the protocol would impact change in practice and patient care. For example if a woman is diagnosed with recurrent UTI/ or present with symptoms of UTI, then hygienic and sanitary issues of care must be dealt with by the health care provider. This will help in educating the class of patients on the issues of proper hygiene and health. Further if a woman is diagnosed with recurrent UTI, then she should be further evaluated for the presence of immunodeficiency, that leads her to the UTI and care can be based upon treatment of the underlying immunodeficiency(Lane and Takhar, 2011) (Wang, Fang and Chen, 2012).

Further if it is noted that there is a reduction of the frequency of antibiotics required or there is a need for low escalation to higher dosage or classes, it will decrease the chances of antibiotic resistance in that woman and may also provide an avenue for cost effective care. This is because in some instances antibiotics for treatment of UTI are not well tolerated which can lead to side effects and increase the burden of disease and hence cost. Apart from that, control of recurrent UTI and its intensity by cranberry supplements

will reduce the risk of septicemia and prevent the chances of end organ failure that can be fatal to the patient. Septicemia or infection of the blood may happen when the pathogens responsible for UTI enters the bloodstream and are carried to other organs to cause infection there, leading to end organ failure. A decreased count of C-reactive protein will indicate that cranberry supplements will reduce the risk of septicemia associated with UTI(Lane and Takhar, 2011) (Wang, Fang and Chen, 2012)

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The evaluation process will be based on a following questionnaire and diagnostic methodology to derive the hard end points. Data will be collected from the patients for one year and the basis of data will be the evaluation remarks of the physician, remarks of the patients based on the symptoms, evaluation of the prescriptions for finding out the status of antibiotics dosage pattern, diagnostic reports of WBC count and C-reactive protein. Data will be collected for four periods in a year to evaluate the interim results and also to justify the dosage of cranberry supplements used and whether the preliminary results indicate that a change in the dosage pattern of cranberry supplements may prove beneficial(Lane and Takhar, 2011) (Wang, Fang and Chen, 2012)

References

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(Lane and Takhar, 2011) (Wang, Fang and Chen, 2012)