Brun ASCN 1989

Proc. Nutr. Soc. Aust. (1992) 17

VITAMINS AND CHANGE IN CERVICAL DYSPLASIA: DESIGN, FOLLOW-UP AND COMPLIANCE IN A SYDNEY STUDY.

D. MACKERRAS*, L. IRWIG*, E. WEISBERG**, M. CARDONA* AND J.M. SIMPSON*.

Evidence from observational studies indicates that one or more components of plant foods may protect against various cancers (Peto et al. 1981) including invasive cervical cancer (Verreault et al. 1989). However, de Vet et al. (1991) found no effect of beta-carotene on the progression rates of minor cervical lesions after administration of 10 mg beta-carotene daily for 3 months in a randomised trial.

We are investigating the effect of daily doses of 30 mg beta-carotene or 500 mg vitamin C on the 2-year progression and regression rates of minor cervical abnormalities. A double-blind, randomised, factorial design is used. Women aged over 18 years newly diagnosed with cervical intraepithelial neoplasia grade I or minor atypia who have chosen to be followed-up rather than treated for the condition are potentially eligible. Recruitment occurs through the Family Planning Association colposcopy clinic. Eligibility is documented by colposcopy, cytology and histology. Women have colposcopies every six months to determine their status. Endpoints of the study are a) evidence of regression to normalcy in two consecutive colposcopies and progression or b) increase in lesion size requiring treatment.

To date, 278 women have been eligible. Of these, 114 agreed to participate but 7 dropped out during the run-in phase prior to randomisation and 8 are currently in the run-in phase. Of the 99 women randomised, 71 have attended follow-up visits at least once, and 35 have attended twice. Two subjects have ceased to take the capsules but continue to have their lesion monitored. No subject has been lost to follow-up.

Compliance is assessed by monthly self-report and six-monthly pill counts. Overall compliance is around 90 % to date. Factors which are related to the high compliance seem to be the monthly phone calls and the presentation of the capsules in blister packs marked with the days of the week. All four types of capsules are identical in appearance and blindness of the study team is maintained by contracting a third party to manage the randomisation procedures.

Four subjects have reached an endpoint (progression) and 21 have had their first normal colposcopy. If the spontaneous progression/regression rates are 30%, 150 women would be needed to detect a 20% difference with a power of 80% at the 0.05 level of significance. However, a larger number of subjects may be needed despite the high compliance and low dropout rates as the disease occurrence rates are lower than expected.

PETO R., DOLL R., BUCKLEY J.D. and SPORN M. (1981) Nature 290:201.

VERREAULT R., CHU J., MANDELSON M. and SHY K. (1989) Int J Cancer 43:1050.

DE VET H., KNIPSCHILD P., WILLEBRAND D., SCHOUTEN H. and STURMANS F. (1991) J Clin Epidemiol 44:273.

* Dept. Public Health, University of Sydney, New South Wales 2006
** The Family Planning Association of N.S.W, Ashfield, New South Wales, 2131.