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Short Report

Double-blind study of traveller's diarrhoea using Nifuroxazide

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Traveller's diarrhoea (T.D.), usually a mild complaint, can seriously curtail a traveller's activities. In 30-50% of cases it is caused by enterotoxigenic *Escherichia coli* (ROSTEN, 1979) which causes a watery diarrhoea lasting 2 or 3 days. T.D. may also be caused by other bacteria and viruses (RYDER *et al.*, 1981), but their exact role remains uncertain.

We tested a wide-spectrum anti-infectious intestinal agent called Nifuroxazide, which has the advantage of being very easy to tolerate. The study was conducted in Morocco during the Atlas car and motorcycle rally between 11 and 21 May 1986. 75 adult French residents, participating in, or organizing, the rally, volunteered to take part. All were in good health and all knew about the study beforehand.

We excluded those who had diarrhoea on the first day of the rally and those who had taken antibiotics during the 10 days before the rally. Subjects were randomized and given a daily dose of 2 capsules of either Nifuroxazide (400 mg per day), or a placebo, for the duration of the rally, from day 1 to day 10. The placebo and the drug were identical in appearance (both prepared by the manufacturer) and the study was double-blind. The capsule administrator was unaware which capsule contained the drug and which was the placebo. The criterion of T.D. was the appearance of at least 3 liquid or non-formed stools per day accompanied by fever, colic or vomiting. The appearance of the ailment and its subsequent treatment automatically eliminated a subject from the study.

Of the participants, 64 were men (85·5%) and 11 women. 83·6% of the subjects were under 40 years old, the average age being 34·5 years (range 20-61). 39 people took Nifuroxazide, 36 the placebo. 30 subjects (4%) developed diarrhoea; of these, 9 were taking Nifuroxazide and 21 were receiving the placebo. This difference is significant ($P<0·01$).

Among the 45 who remained in good health, 30 were taking Nifuroxazide and 15 receiving the placebo. The diarrhoea which did occur was invariably mild and there was no case of dehydration. Once treated, the ailment lasted on average 48 to 72 h. It was not possible to undertake a bacteriological examination.

These results indicate a satisfactory rate of prevention (77%); no side effect was expected, and none occurred.

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