J. steroid Biochem. Vol. 36, No. 3, p. 241, 1990
Printed in Great Britain.

0022-4731/90 $3.00 + 0.00

A PHASE II STUDY OF TOREMIFENE IN CARCINOMA CORPORIS UTERI. PRELIMINARY COMMUNICATION

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Summary—A phase II study of toremifene was started in patients suffering from advanced carcinoma corporis uteri. Minimum duration of treatment was 3 months but with stabilized disease (SD) and remission the treatment is to be continued as long as the treatment response lasts. At present four patients with recurrent carcinoma corpus uteri have been included. Dose level of toremifene is 200 mg per day. At 12 weeks one of the patients has partial remission (PR), two have SD and one progressive disease (PD). There have been no unacceptable side effects.

INTRODUCTION

Endometrial tumors possess functional estrogen receptors (ER) and antiestrogens will induce atrophic changes in endometrial tumor tissue alterations in glycogen accumulation and inhibition of DNA synthesis [1]. Toremifene showed experimentally a competitive inhibition of ER binding with estradiol and was less toxic on a weight basis than tamoxifen [2]. Therefore a phase II study of toremifene was started in advanced carcinoma of corpus uteri.

SUBJECTS AND METHODS

Three patients with histologically verified relapse of adenocarcinoma corporis uteri and one patient with advanced adenocarcinoma corporis uteri have been treated with 200 mg toremifene daily p.o. All patients were previously heavily treated, as indicated in Table 1. ER and progesterone receptors (PgR) were both measured at the start of treatment and after 3 months. After the first 3 months' treatment the frequency of responses was evaluated according to WHO recommendations.

RESULTS AND DISCUSSIONS

Treatment results are given in Table 1. No side effects were detected during the treatment.

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Proceedings of the Toremifene Satellite Symposium held at the *UICC World Cancer Congress*, Budapest, Hungary, 1986.

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Table 1. Patient data and treatment results

Patient characteristics						Results of toremifene treatment:		Duration of response treatment so far
			Duration of response on previous treatment	Receptors (fmol/mg DNA)				
Age (yr)	Stage/grade	Previous treatment		ER	PgR	at 6 weeks treatment	at 12 weeks	
61	I B G 2	Primary operation external irradiation intracavitary irradiation doxorubicin + Cisplatin medroxyprogesterone	0	720	280	SD	SD	3 months
73	II G 3	Primary operation External irradiation	12 months	290	0	SD	SD	2 months
82	I B G 1	Primary operation Medroxyprogesterone	4 yr	0	0	SD	PD	
69	III G 3	External irradiation Tamoxifen	0	90	0	PR		