CMF treated patients DFS was substantially better in those with amenorrhoea.

Elicited side-effects (WHO grades ≥ 1) typical of chemotherapy, e.g. alopecia, nausea/vomiting and infection, were substantially higher with CMF than Zoladex during the 6-month CMF treatment period. Menopausal symptoms, e.g. vaginal dryness and hot flushes, were initially lower with CMF but remained unchanged post-treatment, whereas on cessation of Zoladex, they were markedly reduced to a level below that observed in the CMF group. In summary, in pre-/perimenopausal patients with ER-positive, node-positive early breast cancer, Zoladex demonstrates equivalent efficacy to CMF with a considerably better side-effect profile but without permanent ovarian suppression associated with chemotherapy.

O-114. OVARIAN SUPPRESSION PLUS TAMOXIFEN (TAM) VERSUS CHEMOTHERAPY (CT) IN PATIENTS WITH EARLY BREAST CANCER: RESULTS OF A META-ANALYSIS OF THREE ADJUVANT TRIALS

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A meta-analysis of 3 clinical trials comparing LHRH-A [goserelin (G) or triptorelin (TP)] plus TAM (ET) versus CT (either CMF or CEF) was carried out.

The primary end point of the comparison was survival (OS). Disease-free (DFS) and local DFS were secondary end points. Individual patient (pt) data were collected for 1638 pts, of whom 814 had been assigned to ET and 824 to CT. Virtually all the pts enrolled had ER positive and/or PgR positive tumours. Trial information is provided below.

Assigned treatment	ABC		GROCTA		FASG	
	TAM+G 3-yr	CMF 1,8 ×6	TAM+G 2-yr	Classical CMF ×6	TAM+TP 3-yr	CEF ×6
Randomised pts	526	535	124	120	164	169
Median f.u. time (mos)	55	52	83	83	65	63
Total died (%)	41 (7.9)	50 (9.5)	25 (20.2)	23 (19.2)	10 (6.1)	19 (11.3)
Total relapsed (%)	88 (17.0)	104 (19.8)	50 (40 3)	44 (36.7)	25 (15.3)	37 (22.0)
Locally relapsed (%)	21 (4.1)	41 (7 8)	9 (7.3)	10 (8.3)	7 (4.3)	12 (7.1)

Results are summarized in the table.

Conclusions: The combination of TAM with ovarian suppression appear to be superior to standard CT (either CMF or CEF) in terms of both DFS and local DFS. Both treatments appear to yield comparable results in terms of OS. ET might represent an alternative to CT in breast cancer pts with ER or PgR positive tumours.

	Total	ET	CT	P value	
				Log-rank	Wilcoxon
Total died (%)	168	76 (9.4)	92 (11.3)	0.16	0.12
Total relapsed (%)	348	163 (20.2)	185 (22.8)	0.089	0.056
Locally relapsed (%)	100	37 (4.6)	63 (7.8)	0.004	0.003

O-115. THE ZEBRA STUDY: EARLY BENEFITS IN QUALITY OF LIFE IN GOSERELIN-TREATED *VS* CMF-TREATED PRE-/PERIMENOPAUSAL PATIENTS WITH NODE-POSITIVE EARLY BREAST CANCER

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The large (n = 1640), multicentre, randomized ZEBRA (Zoladex™ Early Breast Cancer Research Association) study has previously reported that goserelin (Zoladex; 3.6 mg every 28 days for 2 years) is as effective as cyclophosphamide/methotrexate/5-fluorouracil (CMF; 6 × 28-day cycles) In pre-/perimenopausal patients with oestrogen receptor (ER) positive early breast cancer. In a protocolled sub-study, quality of life (QoL) was assessed using the Rotterdam Symptom Checklist (RSCL) at 3 and 6 months and 1, 2 and 3 years in patients from 86 centres (goserelin, n = 514 [n = 247 at 3 years]; CMF, n = 496 [n = 243 at 3 years]). Only patients with a baseline score and at least one post-baseline score were included In the analysis. Patient and disease characteristics between the groups were comparable as were all baseline QoL scores. The improvement from baseline in overall QoL score was significantly greater in the goserelin group than the CMF group during the first 3–6 months ($p < 0.0001$). However, at 1, 2 and 3 years, there were no significant differences in overall QoL score between groups. Early QoL benefits for goserelin were also noted for the physical symptom distress, activity level and effort to cope with illness dimensions of the RSCL during the first 3–6 months of therapy, compared with patients receiving CMF ($p < 0.0001$); however, no significant differences in these scores were observed between groups after 6 months. In contrast, the change in score for the hormonal effects dimension was significantly worse in the goserelin group during their 2-year treatment period ($p < 0.01$); however, at 3 years, this trend was reversed. No significant differences were observed between the two treatment groups for the psychological distress or social effects dimensions during or after treatment. Analysis of QoL in the ER-positive sub-group resulted in qualitatively comparable conclusions as the overall QoL population for each RSCL dimension. In summary, goserelin for the treatment of node-positive early breast cancer in pre-/perimenopausal patients offers an improved overall QoL during the CMF 6-month treatment period. Coupled with equivalent efficacy in ER-positive patients, these data support the use of goserelin as an alternative to CMF in this patient population.