BreastCare
Multidisciplinary Journal for Research, Diagnosis and Therapy

Research Article

DOI: 10.1159/000493882

Research Article

ACT-FASTER, a Prospective Cohort Study Exploring Treatment Patterns with Fulvestrant and Exemestane in Postmenopausal Patients with Advanced Hormone Receptor-Positive Breast Cancer under Real-Life Conditions in Germany

Nicolai Maass[a] Helmut Ostermann[b] Kurt Possinger[c] Peter Klein[d] Hans Tesch[e] Lars Mühlenhoff[f] Dirk Bauerschlag[a]

[a]Klinik für Gynäkologie und Geburtshilfe, UKSH, Kiel, [b]Medizinische Klinik und Poliklinik III, Klinikum der Universität München-Grosshadern, München, [c]Medizinische Klinik mit Schwerpunkt Onkologie und Hämatologie, Charité Campus Mitte, Berlin, [d]d.s.h. Statistical Services GmbH, Rohrbach, [e]Onkologische Gemeinschaftspraxis, Frankfurt, and [f]Medical Affairs, AstraZeneca, Wedel, Germany

BreastCare
Multidisciplinary Journal for Research, Diagnosis and Therapy

Research Article

DOI: 10.1159/000493882

Suppl. table 1. Progression-free survival

Analysis statistic	Fulvestrant 1st line (*n* = 176)	Fulvestrant 2nd line (*n* = 163)	Fulvestrant 3rd line (*n* = 93)	Fulvestrant any line (*n* = 432)	Exemestane any line (*n* = 66)
Progression-free survival					
Patients with events, *n* (%)	104 (59.1)	100 (61.3)	61 (65.6)	265 (61.3)	20 (30.3)
Censored patients, *n* (%)	72 (40.9)	63 (38.7)	32 (34.4)	167 (38.7)	46 (69.7)
Quartiles					
25. percentile, months (95% CI)	4.4 (3.4–5.9)	3.5 (2.8–4.1)	3.3 (2.5–4.8)	3.9 (3.3–4.4)	9.9 (2.8–16.7)
50. percentile, months (95% CI)	9.1 (7.7–11.7)	6.8 (5.6–11.2)	6.7 (5.0–8.2)	8.0 (6.7–8.9)	25.4 (12.8–--)
75. percentile, months (95% CI)	24.8 (21.6–33.7)	19.7 (14.0–--)	11.1 (8.7–23.6)	22.7 (16.5–26.5)	Not reached
Time to onset of event[a]					
6 months	67.9 (92)	54.4 (71)	55.1 (40)	60.3 (204)	83.2 (38)
12 months	41.8 (50)	40.5 (43)	24.5 (14)	37.3 (107)	68.4 (23)
18 months	35.5 (32)	28.7 (20)	17.3 (7)	29.3 (59)	60.8 (14)
24 months	25.5 (16)	20.8 (10)	13.9 (3)	21.4 (29)	55.7 (8)
30 months	18.9 (9)	15.6 (4)	13.9 (0)	16.2 (13)	30.9 (2)
p-value (log-rank) Overall: 3 lines for Fulvestrant, exemestane			$p < 0.0001$		

CI confidence interval

[a] Percentage of patients without event at the respective time points is summarised with Kaplan–Meier estimates and (number at risk)

BreastCare
Multidisciplinary Journal for Research, Diagnosis and Therapy

Research Article

DOI: 10.1159/000493882

Suppl. table 2. Tumor response

	Fulvestrant 1st line (*n* = 176)	Fulvestrant 2nd line (*n* = 163)	Fulvestrant 3rd line (*n* = 93)	Fulvestrant any line (*n* = 432)	Exemestane any line (*n* = 66)
Objective response (CR/PR)					
Patients without objective response, *n* (%)	132 (75.0%)	148 (90.8%)	83 (89.2%)	363 (84.0%)	58 (87.9%)
Patients with objective resonse, *n* (%)	44 (25.0%)	15 (9.2%)	10 (10.8%)	69 (16.0%)	8 (12.1%)
Clinical benefit (CR/PR/SD)					
Patients without clinical benefit, *n* (%)	125 (71.0%)	124 (76.1%)	70 (75.3%)	319 (73.8%)	46 (69.7%)
Patients with clinical benefit, *n* (%)	51 (29.0%)	39 (23.9%)	23 (24.7%)	113 (26.2%)	20 (30.3%)

CR complete response, *PR* partial response

If at a visit results were reported from more than one assessment method, the most unfavourable result was used for the analysis

BreastCare
Multidisciplinary Journal for Research, Diagnosis and Therapy

Research Article

DOI: 10.1159/000493882

Suppl. table 3. Number of patients with AEs, SAEs and ADRs

Patients, *n* (%)	Fulvestrant 1st line (*n* = 176)	Fulvestrant 2nd line (*n* = 163)	Fulvestrant 3rd line (*n* = 93)	Fulvestrant any line (*n* = 432)	Exemestane any line (*n* = 66)
Number of patients with					
Adverse events (AE and SAE data combined)	52 (29.5%)	35 (21.5%)	23 (24.7%)	110 (25.5%)	18 (27.3%)
Drug related AEs (AE and SAE data combined)	22 (12.5%)	22 (13.5%)	13 (14.0%)	57 (13.2%)	12 (18.2%)
Serious AEs (AE and SAE data combined)	33 (18.8%)	17 (10.4%)	11 (11.8%)	61 (14.1%)	9 (13.6%)
Serious AEs (AE data only)*	8 (4.5%)	3 (1.8%)	2 (2.2%)	13 (3.0%)	3 (4.5%)
Drug related serious AEs (AE and SAE data combined)	3 (1.7%)	2 (1.2%)	1 (1.1%)	6 (1.4%)	1 (1.5%)
AEs leading to treatment discontinuation (AE and SAE data combined)	8 (4.5%)	4 (2.5%)	3 (3.2%)	15 (3.5%)	5 (7.6%)
Study discontinuation due to AE reported	2 (1.1%)	2 (1.2%)	3 (3.2%)	7 (1.6%)	1 (1.5%)
One patient with no referring AE or SAE**	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.2%)	0 (0.0%)
Serious AEs with fatal outcome	12 (6.8%)	4 (2.5%)	1 (1.1%)	17 (3.9%)	0 (0.0%)

AE adverse event, *SAE* serious adverse event, *AEs and SAEs were documented on separate forms. For SAEs documented in AE data only, seriousness was mentioned in AE form, but no corresponding SAE form was filled. **For one patient therapy discontinuation due to an AE was documented, however no corresponding AE/SAE form was filled.

BreastCare
Multidisciplinary Journal for Research, Diagnosis and Therapy

Research Article

DOI: 10.1159/000493882

Suppl. table 4. Most frequently reported AEs related to treatment with fulvestrant or exemestane (AE and SAE data combined) – incidence of AE by group

Patients, *n* (%)	Fulvestrant 1st line (*n* = 176)	Fulvestrant 2nd line (*n* = 163)	Fulvestrant 3rd line (*n* = 93)	Fulvestrant any line (*n* = 432)	Exemestane any line (*n* = 66)
Gastrointestinal disorders	6 (3.4%)	4 (2.5%)	3 (3.2%)	13 (3.0%)	2 (3.0%)
General disorders and administration site conditions	5 (2.8%)	9 (5.5%)	2 (2.2%)	16 (3.7%)	4 (6.1%)
Musculoskeletal and connective tissue disorders	6 (3.4%)	10 (6.1%)	1 (1.1%)	17 (3.9%)	5 (7.6%)
Skin and subcutaneous tissue disorders	7 (4.0%)	1 (0.6%)	4 (4.3%)	12 (2.8%)	2 (3.0%)

AE adverse event, *SAE* serious adverse event

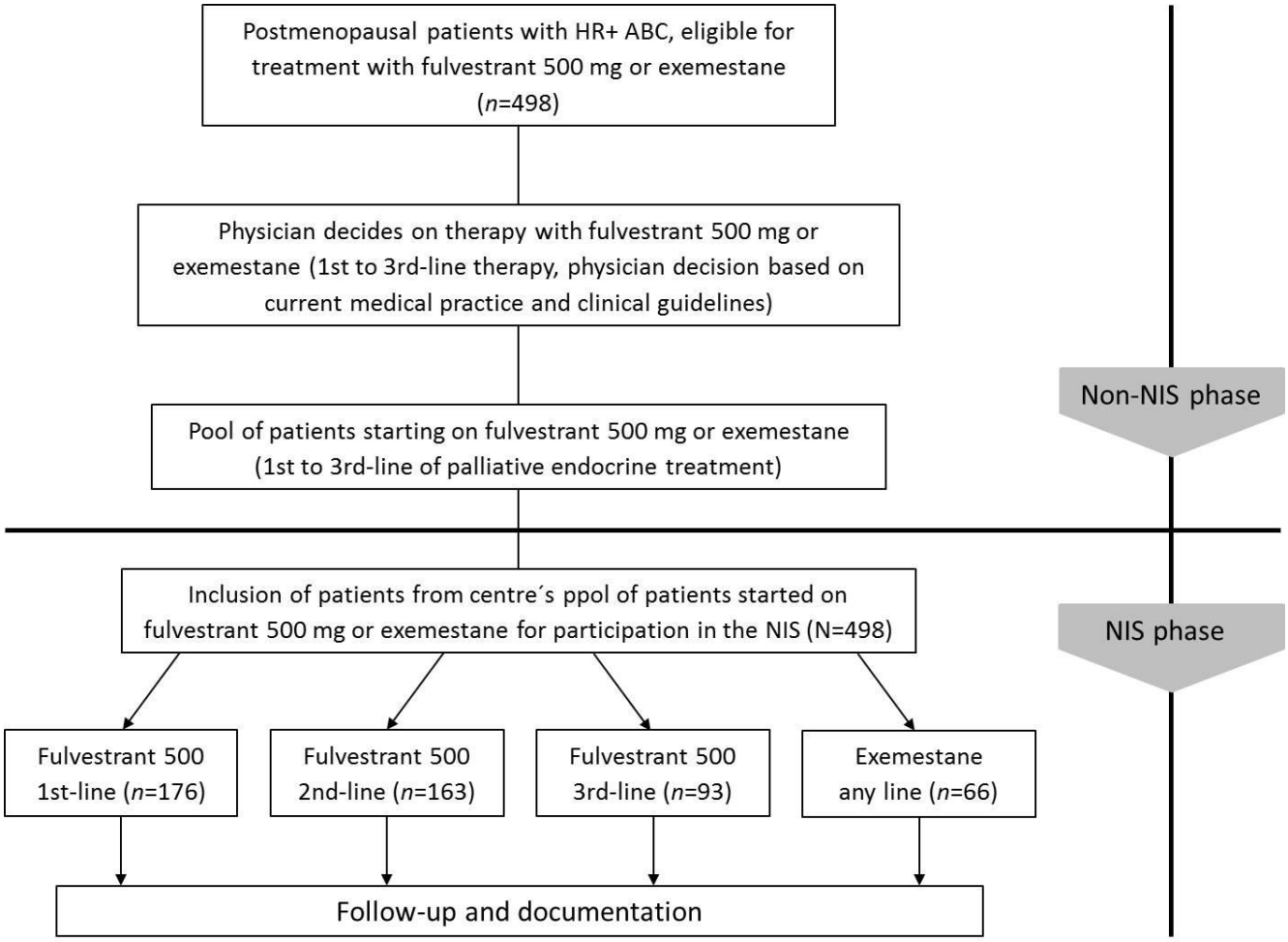
Each group counted only once per patient

BreastCare
Multidisciplinary Journal for Research, Diagnosis and Therapy

Research Article

DOI: 10.1159/000493882

Suppl. fig. 1. Patient distribution.

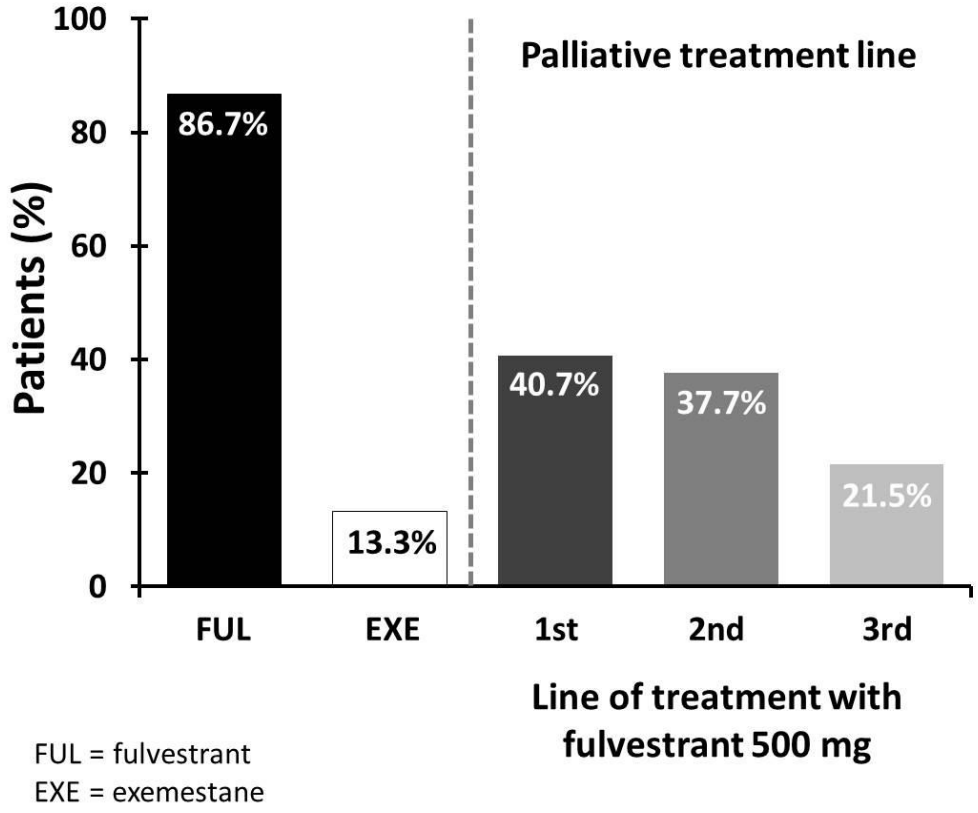


BreastCare
Multidisciplinary Journal for Research, Diagnosis and Therapy

Research Article

DOI: 10.1159/000493882

Suppl. fig. 2. Proportion of patients treated by therapy and treatment line.



FUL = fulvestrant
EXE = exemestane