HEART FAILURE

TRIALS

NUMBER OF PARTICIPANTS	NUMBER OF WOMEN	PERCENTAGE OF WOMEN	MEAN AGE	MEAN FOLLOW-UP (YEARS)	TRIALS WITH ANALYSIS BY GENDER N, (%)
46,141	12,834	27.8%	69.2	2.4	8/11 (72.7%)

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		(Country)	**mean ± sd, range**	**TOTAL (WOMEN n,%)**	**DURATION**			**TOTAL (WOMEN n,%) (MEN n,%)**	**(CI) P (WOMEN) (MEN)**	
PEP-CHF (Cleland et al [147])	OCT 2006	International trial with significant European component in patients with a diagnosis of heart failure, treated with diuretics and an echocardiogram suggesting diastolic dysfunction and excluding substantial LV systolic dysfunction or valve disease	76 ± 5 (Range: 72 – 79)	850 **(WOMEN : 472, 55.5%)** (MEN 378)	2.1 years (IQR: 11.5 - 2.8)	PLACEBO vs. PERINDOPRIL (4 mg/day)	All-cause mortality or unplanned heart failure related hospitalization with a minimum follow-up of 1 year	*Entire duration of follow-up:* TOTAL: PLACEBO 107 (25.1%) PERINDOPRIL 100 (23.6%) *First year of follow-up:* TOTAL: PLACEBO 46(10.8%) PERINDOPRIL 46 10.8%) **WOMEN : PLACEBO 39/242 (16.1%) PERINDOPRIL 25/227 (11.0%)** MEN: PLACEBO 26/184 (14.1%) PERINDOPRIL 21/197 (10.7%)	*Entire duration of follow-up:* HR_{TOTAL} = 0.92 [95% CI: 0.70-1.21] P = 0.545 *First year of follow-up:* HR_{TOTAL} = 0.69 [95% CI: 0.47–1.01] P = 0.055 **HR_{WOMEN} = 0.67 [95% CI: 0.40-1.10**] HR_{MEN} = 0.73 [95% CI: 0.41-1.31] **$P_{INTERACTION}$ = 0.800**	Younger patients and those with a history of MI or hypertension tended to obtain greater benefit from PERINDOPRIL. **Hazard ratios for men and women were similar indicating that the effect of perindopril on the outcome was not significant**

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EVEREST Outcome Trial (Konstam et al [148])	MAR 2007	International trial with significant European component in patients within 2 short-term clinical status studies, who were hospitalized with heart failure	65.9 ± 11.7 TOLVAPTAN 65.6 ± 12.0 PLACEBO	4133 **(WOMEN: 1058, 25 %)** (MEN 3075)	Median of 9.9 months	Within 48 hours of admission, patients ORAL TOLVAPTAN (30 mg once per day) vs. PLACEBO, in addition to standard therapy.	Dual primary end points: *All-cause mortality (superiority and noninferiority) and Cardiovascular death or hospitalization for heart failure (superiority only)*	*All-cause mortality:* TOTAL: PLACEBO: 543 (26.3%) TOLVAPTAN: 537 (25.9%) **(WOMEN: PLACEBO: 129/506 (25.5%) TOLVAPTAN: 122/552 (24.1%))** (MEN: TOLVAPTAN: 415/1520 (27.3%) PLACEBO: 414/1555 (26.6%)) *Cardiovascular death or hospitalization for heart failure:* TOTAL: TOLVAPTAN: 871 (42.0%) PLACEBO: 829 (40.2%) **(WOMEN: TOLVAPTAN 219/552 (39.7%) PLACEBO 191/506 (37.7%))** (MEN: TOLVAPTAN 652/1520 (42.8%) PLACEBO 638 /1555 (41.0%))	*All-cause mortality*: HR_{TOTAL} = 0.98 [95% CI: 0.87-1.11] $P_{SUPERIORITY}$=0.68 $P_{NON\ INFERIORITY}$ <0.01 *Cardiovascular death or hospitalization for heart failure:* HR_{TOTAL} = 1.04 [95% CI: 0.95-1.14] $P_{SUPERIORITY}$ = 0.55	**No gender difference in the outcomes. Tolvaptan was significantly non-inferior to placebo on all-cause mortality in both gender The effects on cardiovascular death and hosptalization for heart failure were not significant in both gender**

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EVEREST Clinical Status Trials (Gheorghiade et al [149])	MAR 2007	Two identical prospective short-term trials (trial A) and (trial B) with significant European component conducted in patients hospitalized with heart failure.	TRIAL A TOLVAPTAN 65.8 ± 11.7 [range: 24-94] PLACEBO 65.6 ± 11.9) [range: 23-92] TRIAL B TOLVAPTAN 66.0 ± 11.7 [range: 22-94] PLACEBO 65.6 ± 12.2 [range: 18-93]	TRIAL A 2048 **(WOMEN: 511, 25%)** (MEN: 1537) TRIAL B 2085 **(WOMEN: 547, 26%)** (MEN: 1538)	median of 9.9 months	TOLVAPTAN (30 mg/d) or MATCHING PLACEBO, within 48 hours of admission	Changes in global clinical status based on a visual analog scale or body weight at day 7 or discharge if earlier		TRIAL A TOLVAPTAN: mean [SD] = 1.06 [0.43] vs. PLACEBO mean [SD]= 0.99 [0.44] P < 0.001 TRIAL B TOLVAPTAN: mean [SD] = 1.07 [0.42] vs. PLACEBO mean [SD] = 0.97 [0.43] P < 0.001	**Results by gender not reported**

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CHARM (O'Meara et al [150])	JUNE 2007	Consisted of 3 independent but related trials in which patients with New York Heart Association (NYHA) class II to IV HF. Patients with an LVEF ≤ 0.40 who were intolerant of an ACE inhibitor were enrolled in *CHARM-Alternative*. Patients with an LVEF ≤ 0.40 who were taking an ACE inhibitor were enrolled in *CHARM-Added* . In *CHARM-Added*, patients in NYHA class II had to have had a hospital admission for a cardiac reason in the previous 6 months (this increased the proportion of NYHA class III/IV patients in *CHARM-Added*). Patients with an LVEF >0.40 were randomized in *CHARM-Preserved.*	**WOMEN 67.8 ± 0.2** MEN : 64.4 ± 0.2 **Female Versus Male Comparison: mean differences for age (95% CI) 3.4 (2.9 to 3.9) P<0.001**	7599 **WOMEN 2400, 31.6%** MEN 5199 *CHARM-Alternative:* n=2028, **WOMEN 21%** *CHARM-Added:* n=2548, **WOMEN 32%** *CHARM-Preserved:* n=3023, **WOMEN 40%**	Median 38 months	CANDESARTAN vs. PLACEBO	For each of the 3 component trials: death due to a cardiovascular cause or unplanned admission to the hospital for the management of worsening HF. *In the overall program:* death due to any cause	CV death or HF hospitalization TOTAL 2460 **(WOMEN 730 (30.4%))** (MEN 1730 (33.3%)) Death due to any cause TOTAL 1831 **WOMEN 515 (21.5%))** (MEN 1316 (25.3%))	CV death or HF hospitalization $HR_{ADJUSTED}$ = 0.83 [95% CI: 0.76 - 0.91] P < 0.001 $HR_{UNADJUSTED}$ = 0.91 [95% CI: 0.83 - 0.99] P=0.032 Death due to any cause $HR_{UNADJUSTED}$ = 0.85 [95% CI: 0.76 - 0.94] P=0. 001 $HR_{ADJUSTED}$ = 0.77 [95% CI: 0.69 - 0.86] P<0.001	**A reduction in cardiovascular death or HF hospitalization was associated with the use of candesartan in both men and women in CHARM overall (P for interaction = 0.89), as was the effect of candesartan on all-cause mortality (P for interaction = 0.98)**

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CORONA (Kjekshus et al [151])	NOV 2007	European trial with significant European component in patients at least 60 years of age with New York Heart Association class II, III, or IV ischemic, systolic heart failure	73 ± 7.0 PLACEBO 73 ± 7.1 ROSUVASTATIN	5011 **(WOMEN: 1180, 24%)** (MEN: 3831)	Median of 32.8 months	ROSUVASTATIN (10 mg daily) vs. PLACEBO	Death from cardiovascular causes or nonfatal myocardial infarction or nonfatal stroke	TOTAL: ROSUVASTATIN: 692 732 PLACEBO (**WOMEN :** **155 (10.8%)** **PLACEBO** **VS.** **138 (9.3%)** **ROSUVASTATIN)** (MEN: 577 (12.8%) PLACEBO 554 (12.0%) ROSUVASTATIN)	HR = 0.92 [95% CI: 0.83 - 1.02] P = 0.12	**The lack of benefit of treatment was consistent across all prespecified subgroups, included gender, with no indication of harm in any subgroup**

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GISSI-HF (Tavazzi et al[152])	OCT 2008	Trial in patients aged 18 years or older with chronic heart failure of New York Heart Association class II–IV, irrespective of cause and left ventricular ejection fraction, enrolled in 326 cardiology and 31 internal medicine centres in Italy	68 ± 11	4574 **(WOMEN: 1032, 23.6%)** (MEN 3542)	Median of 3.9 years (IQR 3.0–4.4)	PLACEBO vs. ROSUVASTATIN (10 mg daily).	Time to death and time to death or admission to hospital for cardiovascular reasons (coprimary)	Death from any cause: PLACEBO 644 (28%) vs. ROSUVASTATIN 657 (29%) Death or admission to hospital for cardiovascular reasons: PLACEBO 1283 (56%) vs. ROSUVASTATIN 1305 (57%)	Death from any cause: $HR_{ADJUSTED}$ = 1.00 [95.5 % CI : 0.898 – 1.122] P = 0.943 $HR_{UNADJUSTED}$ = 1.03 [95.5% CI: 0.917–1.145] p = 0.660 Death or admission to hospital for cardiovascular reasons: $HR_{ADJUSTED}$ = 1.01 [99% CI: 0.908–1.112] P = 0.903 $HR_{UNADJUSTED}$ =1.02 [99% CI: 0.923–1.130] P=0.594	**Results by gender not reported. Adjustment also for sex in the Cox proportional hazards model**

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GISSI-HF (Tavazzi et al[153])	OCT 2008	Randomised, double-blind, placebo-controlled trial in patients with chronic heart failure of New York Heart Association class II–IV, irrespective of cause and left ventricular ejection fraction enrolled in 326 cardiology and 31 internal medicine centres in Italy	67 ± 11	TOTAL 6975 **(WOMEN 1516, 21.7%)** (MEN 5459)	MEDIAN OF 3.9 YEARS (IQR : 3.0–4.5)	PLACEBO vs. n-3 PUFA (1 g daily)	Time to death, and time to death or admission to hospital for cardiovascular reasons (coprimary)	Death from any cause: PLACEBO: 1014 (29%) vs. n-3 PUFA: 955 (27%) Death or admission to hospital for cardiovascular reasons: PLACEBO: 2053 (59%) vs. n-3 PUFA: 981 (57%)	Death from any cause: $HR_{ADJUSTED}$= 0.91 [95.5% CI: 0.833–0.998] P=0.041 $HR_{UNADJUSTED}$ = 0.93 [95.5% CI : 0.852 - 1.021] P = 0.124 Death or admission to hospital for cardiovascular reasons: $HR_{ADJUSTED}$= 0.92 [99% CI: 0.849–0.999] P=0.009 $HR_{UNADJUSTED}$ = 0.94 [99% CI: 0.869–1.022] P=0.059	**Results by gender not reported**

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BEAUTIFUL (Fox et al [154])	SEPT 2008	International trial with significant European component in patients who had coronary artery disease and a left-ventricular ejection fraction of less than 40%.	65.2 ± 8.5	TOTAL: 10917 **(WOMEN: 1870, 17%)** (MEN 9047)	Median of 19 months (IQR: 16–24)	PLACEBO (in addition to appropriate cardiovascular medication) vs. IVABRADINE (5 mg, with the intention of increasing to the target dose of 7·5 mg twice a day)	Cardiovascular death or admission to hospital for acute myocardial infarction or admission to hospital for new onset or worsening heart failure	TOTAL: PLACEBO 832 (15.3%) vs. IVABRADINE 844 (15.4%) **(WOMEN : PLACEBO 132 (9.2%) vs. IVABRADINE 152 (10.5%))** (MEN : PLACEBO 700 (10.0%) vs. IVABRADINE 692 (9.8%))	HR_{TOTAL} =1.00 [95% CI: 0.91–1.1] P=0.94 **HR_{WOMEN} = 1.14** HR_{MEN} = 0.98 **$P_{INTERACTION}$ = 0.226**	**No significant effects of treatment in both men and women**

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I-PRESERVE (Massie et al [155])	DEC 2008	International trial with significant European component in patients who were at least 60 years of age and had New York Heart Association class II, III, or IV heart failure and an ejection fraction of at least 45%	72 ± 7	TOTALE: 4128 **(WOMEN: 2491, 60%)** (MEN 1637)	Mean of 49.5 months	PLACEBO vs. IRBESARTAN (300 mg / day)	Death from any cause or hospitalization for a cardiovascular cause (heart failure, myocardial infarction, unstable angina, arrhythmia, or stroke)	TOTAL: PLACEBO 763 (37%) vs. IRBESARTAN 742 (36%) **(WOMEN : PLACEBO 420/1264 (33%) vs. IRBESARTAN 392/1227 (32%))** (MEN : PLACEBO 343/797 (43%) vs. IRBESARTAN 350/840 (42%))	HR_{TOTAL} = 0.95 [95% CI: 0.86 - 1.05] P = 0.35 **HR_{WOMEN} = 0.94 [95% CI: 0.82–1.08]** HR_{MEN} =0.96 [95% CI: 0.83–1.12] **$P_{INTERACTION}$ = 0.78**	**No significant effects of treatment in both men and women**

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TIME-CHF (Pfisterer et al [156])	JAN 2009	International trial conducted at 15 centers in Switzerland and Germany and included patients aged 60 years or older with systolic heart failure (ejection fraction _45%), New York Heart Association (NYHA) class of II or greater, prior hospitalization for heart failure within 1 year, and N-terminal BNP level of 2 or more times the upper limit of normal	77 ± 8 Symptom-Guided 76 ± 7 N-Terminal BNP–Guided	TOTAL: 499 **(WOMEN: 172, 34.5%)** (MEN 327)	18-month	N-terminal BNP–guided vs. symptom-guided heart failure therapy	18-month survival free of all-cause hospitalizations and quality of life as assessed by structured validated questionnaires.	Rates of survival free of all-cause hospitalizations : 41%N-terminal BNP vs. 40%, symptom-guided therapy **(WOMEN: N-Terminal BNP–Guided: 80 vs. Symptom-Guided: 92)** (MEN: N-Terminal BNP–Guided: 171 vs. Symptom-Guided: 156)	HR = 0.91 [95% CI: 0.72-1.14] P = 0.39 **$P_{INTERACTION} < 0.05$**	**Therapy guided by N-terminal BNP significantly improved free survival in women but not in men.**

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WATCH (Massie et al [157])	MAR 2009	International trial with significant European component (318 came from 29 sites in the United Kingdom) in patients with symptomatic heart failure for at least 3 months who were in sinus rhythm and had left ventricular ejection fraction of ≤ 35	63 ± 11	TOTAL: 1587 **(WOMEN: 234, 15%)** (MEN 1353)	Mean of 1.9 years	Open-label WARFARIN (target international normalized ratio of 2.5 to 3.0) and double-blind treatment with either ASPIRIN (162 mg once daily) or CLOPIDOGREL (75 mg once daily)	All-cause mortality, nonfatal MI, or nonfatal stroke	TOTAL: WARFARIN 106 (19.6%) ASPIRIN 108 (20.7%) CLOPIDOGREL 113 (21.6%)	WARFARIN vs. ASPIRIN: HR = 0.98 [95% CI: 0.86 - 1.12] P=0.77 CLOPIDOGREL vs. ASPIRIN: HR =1.08 [95% CI: 0.83- 1.40] P=0.57 WARFARIN vs. CLOPIDOGREL: HR = 0.89 [95% CI: 0.68 - 1.16] P= 0.39	**Results by gender not reported**

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HF-ACTION (O'Connor et al [158])	APR 2009	International trial in medically stable outpatients with heart failure with left ventricular ejection fraction of 35% or less, recruited from 82 centers in the United States, Canada, and France.	USUAL CARE 59.3 (IQR 51.1 - 68.2) vs. EXERCISE TRAINING: 59.2 (IQR 51.2 - 67.8)	TOTAL: 2331 **(WOMEN: 661, 28%)** (MEN: 1670)	Median of 30.1 months (range: 1 - 4 years)	USUAL CARE PLUS AEROBIC EXERCISE TRAINING (consisting of 36 supervised sessions followed by home-based training) vs. USUAL CARE ALONE	All-cause mortality or hospitalization	TOTAL: EXERCISE TRAINING: 759 (65%) vs. USUAL CARE: 796 (68%) **WOMEN: 420/661 (63.5%)** MEN: 1135/1670 (68.5%)	HR_{TOTAL} = 0.93 [95% CI 0.84 - 1.02] P=0.13 Adjusted for key prognostic factors: HR = 0.89 [95% CI: 0.81 - 0.99] P = 0.03 **HR_{WOMEN} = 0.83 [95% CI: 0.68-1.00]** HR_{MEN} = 0.97 [95% CI: 0.87-1.09] $P_{INTERACTION}$ = 0.17	**There is tendency for a better effect of training on the outcome in women, but no significant interaction**

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HF-ACTION (Flynn et al [159])	APR 2009	International trial in medically stable outpatients with heart failure with left ventricular ejection fraction of 35% or less, recruited from 82 centers in the United States, Canada, and France.	59.3 (IQR 51.1-68.2) Usual Care vs. 59.2 (IQR 51.2-67.8) Exercise Training	TOTAL: 2331 **(WOMEN: 661, 28%)** (MEN 1670)	Median of 2.5 years	USUAL CARE PLUS AEROBIC EXERCISE TRAINING (consisting of 36 supervised sessions followed by home-based training) vs. USUAL CARE ALONE	Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary scale and key subscales at baseline		At 3 months: USUAL CARE PLUS EXERCISE TRAINING: mean= 5.21 [95% CI: 4.42 - 6.00] P<0.001 USUAL CARE ALONE mean= 3.28 [95% CI: 2.48 - 4.09] P<0.001 Between-Group Differences in Changes = 1.93 [95% CI: 0.84 - 3.01] P<0.001 After 3 months, there were no further significant changes in KCCQ score for either group.	**No significant subgroup interactions for sex (P=0.26)**

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SENIORS (van Veldhuisen et al [160])	JUN 2009	Subanalysis of the SENIORS trial in patients with stable HF	ALL PATIENTS: 76.1 ± 4.7 LVEF <35%: 76.1± 4.6 LVEF >35%: 76.1 ± 4.7	TOTAL: 2111 **(WOMEN: 780, 37.0%)** (MEN: 1331) EF ≤35%: TOTAL 1,359, 64% **(WOMEN 405, 29.8%)** (MEN: 954) EF >35%: TOTAL: 752, 36% **(WOMEN: 375, 49.9%)** (MEN: 377)	21 months	PLACEBO vs. NEBIVOLOL	All-cause mortality or cardiovascular hospitalizations.	EF ≤ 35%: TOTAL: 465 (34.2%) NEBIVOLOL: 218 (32.2%) PLACEBO: 247 (36.3%) EF >35% TOTAL: 235 (31.2%) NEBIVOLOL: 110 (29.0%) PLACEBO: 125 (33.6%)	EF ≤ 35% HR = 0.86 [95% CI: 0.72–1.04] EF >35% HR = 0.81 [95% CI: 0.63–1.04]	**Patients with preserved EF were more often women (49.9% vs. 29.8%) and had less advanced HF, more hypertension and fewer prior myocardial infarctions (all p<0.001).** The effect of betablockade (with nebivolol) is similar in HF patients with preserved and impaired EF. There was no significant interaction between treatment effect and EF when the latter was taken as a continuous variable (p = 0.720). **Results by gender not reported**

META-ANALYSIS

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		(Country)	**mean ± sd, range**	**TOTAL (WOMEN n,%)**	**DURATION**			**TOTAL (WOMEN n,%) (MEN n,%)**	**(CI) P (WOMEN) (MEN)**	
Cardiac resynchronization therapy effect on mortality (Rivero-Ayerza et al [161])	NOV 2006	Meta-analysis of five randomized controlled studies in patients with advanced HF and a depressed left ventricular systolic performance	mean age 66 years	2371 **WOMEN: 29%**	Range 3-29 months	CRT ALONE (without a combined defibrillator function) vs. OPTIMAL PHARMACOLOGICAL THERAPY	Death	*All-cause mortality:* CRT-treated 227 (16.9 %) vs. Optimal Pharmacological Therapy 213 (20.7%). (absolute reduction of 3.8%) *Heart Failure Mortality:* CRT-treated 90 (6.7%) vs. Optimal Pharmacological Therapy 100 (9.7%)	*All-Cause Mortality:* OR = 0.71 [95% CI: 0.57 - 0.88] Overall Effect: P=0.002 *Mortality due to progressive HF :* OR = 0.62 [95% CI: 0.45 - 0.84] Overall Effect: P=0.003	No effect on sudden cardiac death (SCD) was observed with CRT. **Results by gender not reported**