Clinical trials of hormonal replacement therapy for cardiovascular prevention in all type of patients

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1 hormonal replacement therapy

Trial	Treatments	Patients	Trials design and methods
combined estrogen and progestogen vs placebo			
Schulman (NHLBI) (estrogen-progestogen) , 2002 [NCT00000601] n=94/99 follow-up: 6 months	intravenous estrogen followed by oral conjugated estrogen plus medroxyprogesterone for 21 days versus placebo	Postmenopausal women with unstable angina	Parallel groups double blind USA, Brazil
EAGAR , 2006 [NCT00000605] n=44/51 follow-up: 33 months	estradiol +/-medroxyprogesterone versus placebo	Postmenopausal women who had undergone coronary artery bypass graft	Parallel groups double blind USA, Canada
ERA (estrogen plus medroxyprogesterone) , 2000 [NCT00000549] n=104/105 follow-up: 3.6y	estrogen plus medroxyprogesterone acetate (0.625 mg of conjugated estrogen plus 2.5 mg of medroxyprogesterone acetate per day) versus placebo	Postmenopausal women with established coronary atherosclerosis	Parallel groups double-blind USA
EVTET , 2000 n=71/69 follow-up: 24 months	2 mg estradiol plus 1 mg norethisterone acetate, 1 tablet daily versus placebo	postmenopausal women younger than 70 years who had suffered previous DVT or PE	Parallel groups double-blind Norway
Hall , 1998 n=40/20 follow-up: 1 y	transdermal 17 beta-estradiol at a dose of 50 micrograms per 24 h alone for 18 days followed by 10 days of combined treatment with medroxyprogesterone acetate (MPA) 5 mg orally versus placebo	postmenopausal women with coronary artery disease aged 4475 years	Parallel groups double-blind Sweden
HERS , 1998 [NCT00319566] n=1380/1383 follow-up: 4.1 y	Premarin .625 mg daily plus medroxyprogesterone 2.5 mg daily versus placebo	women with coronary disease, younger than 80 years, and postmenopausal with an intact uterus	Cross over double-blind US

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Trial	Treatments	Patients	Trials design and methods
WAVE , 2002 [NCT00000555] n=210/213 follow-up: 2.8 y	0.625 mg/d of conjugated equine estrogen (plus 2.5 mg/d of medroxyprogesterone acetate for women who had not had a hysterectomy) versus placebo	Postmenopausal women, up to age 86, with angiographically documented coronary artery disease of at least 15 percent, but no more than 75 percent occlusion	Factorial plan double blind United States, Canada
WELL-HART (estrogen-progestin) , 2003 [NCT00000559] n=74/76 follow-up: 3.3 y	17 beta-estradiol plus sequentially administered medroxyprogesterone acetate versus placebo	Postmenopausal women with angiographically-documented coronary disease	double blind USA
WHI , 2002 n=8506/8102 follow-up: 5.2 y	conjugated equine estrogens, 0.625 mg/d, plus medroxyprogesterone acetate, 2.5 mg/d, in 1 tablet versus placebo	postmenopausal women aged 50-79 years with an intact uterus at baseline	Factorial plan double-blind USA
WHISP , 2006 n=49/51 follow-up: 1 y	oral oestradiol-17beta 1 mg plus norethisterone acetate 0.5 mg daily versus placebo	post-menopausal women >55 years were enrolled between 2 and 28 days after an acute coronary syndrome	Parallel groups double-blind UK
WISDOM , 2007 [ISRCTN63718836] n=2196/2189 follow-up: 11.9 months	combined estrogen and progestogen versus placebo	postmenopausal women aged 50-69	Parallel groups double-blind UK, Australia, New Zealand
error vs placebo			
PHASE *ongoing* n=NA	-	-	
estrogen vs placebo			
EPAT , 2001 n=111/111 follow-up: 2 y	micronized 17beta-estradiol (1 mg/d) versus placebo	postmenopausal women 45 years of age or older without preexisting cardiovascular disease and with low-density lipoprotein cholesterol levels of 3.37 mmol/L or greater (>/=130 mg/dL)	Parallel groups double-blind USA
ERA (estrogen alone) , 2000 [NCT00000549] n=100/105 follow-up: 3.6y	estrogen alone (0.625 mg of conjugated estrogen per day) versus placebo	Postmenopausal women with established coronary atherosclerosis	Parallel groups double-blind USA
ESPRIT , 2002 n=513/504 follow-up: 24 months	oestradiol valerate 2 mg daily versus placebo	postmenopausal women, age 50-69 years who had survived a first myocardial infarction	Parallel groups double-blind England and Wales

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Trial	Treatments	Patients	Trials design and methods
Schulman (NHLBI) (estrogen alone) , 2002 [NCT00000601] n=100/99 follow-up: 6 months	intravenous followed by oral conjugated estrogen for 21 days, intravenous estrogen followed by oral conjugated estrogen plus medroxyprogesterone for 21 days versus placebo	Postmenopausal women with unstable angina	Parallel groups double blind USA, Brazil
WELL-HART (estrogen alone) , 2003 [NCT00000559] n=76/76 follow-up: 3.3 y	micronized 17beta-estradiol alone versus placebo	Postmenopausal women with angiographically-documented coronary disease	Parallel groups double blind USA
WEST , 2001 n=337/327 follow-up: 2.8 y	estrogen therapy (1 mg of estradiol-17beta per day) versus placebo	postmenopausal women who had recently had an ischemic stroke or transient ischemic attack	Parallel groups double-blind USA
hormonal replacement therapy vs placebo			
PEPI , 1995 [NCT00000466] n=875 follow-up: 3 years	estrogen replacement therapy versus placebo	Postmenopausal women, ages 45 to 64	Parallel groups double blind USA

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2 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

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