

Clinical trials of phosphodiesterase III inhibitors for heart failure in all type of patients

TrialResults-center www.trialresultscenter.org

1 Phosphodiesterase III inhibitors

Trial	Treatments	Patients	Trials design and methods
Amrinone vs placebo			
AMTG , 1985 n=NA follow-up: 3 months	Amrinone <600mg/day versus placebo	patients with heart failure NYHA III/IV	Parallel groups double blind
Enoximone vs placebo			
EMOTE , 2007 n=101/100 follow-up: 26 weeks	enoximone versus placebo	patients with ultra-advanced heart failure requiring IV inotropic therapy	Parallel groups double blind US
Cowley , 1994 n=75/76 follow-up: 12 months	Enoximone 300mg/d versus placebo	NYHA III,IV	Parallel groups double blind
EMTG , 1990 n=50/52 follow-up: 4 months	Enoximone <450 mg/d versus placebo	NYHA II, III	Parallel groups double blind
ESG , 2000 n=70/35 follow-up: 3 months	Enoximone 75-150 mg/d versus placebo	NYHA II, III	Parallel groups double blind
ESSENTIAL (I and II) , 2009 [NCT00051285] n=926/928 follow-up: 16.6 mo (median)	enoximone titrated to 50 mg three times daily versus placebo	Patients with New York Heart Association class IIIIV HF symptoms, left ventricular ejection fraction 30% , and one hospitalization or two ambulatory visits for worsening HF in the previous year	Parallel groups double blind Europe and North andSouth America
Lardoux , 1987 n=30/13 follow-up: 3 months	Enoximone 150, 300mg/d versus placebo	NYHA NA	Parallel groups double blind
WESG , 1991 n=108/56 follow-up: 3 months	Enoximone 150, 300 mg/d versus placebo	NYHA II, III	Parallel groups double blind
Flosequinan vs placebo			
REFLECT II , 1991 n=207/104 follow-up: 3 months	-	NYHA II-IV	Parallel groups double blind
Cowley , 1993 n=64/71 follow-up: 4 months	Flosequinan 125mg/d versus placebo	NYHA II, III	Parallel groups double blind

continued...

Trial	Treatments	Patients	Trials design and methods
FACET , 1993 n=212/110 follow-up: 4 months	Flosequinan 100 and 150 mg/d versus placebo	NYHA II, III	Parallel groups double blind
REFLECT , 1993 n=93/100 follow-up: 3 months	Flosequinan 100mg/d versus placebo	NYHA II,III	Parallel groups double blind
ibopamine vs placebo			
PRIME II , 1997 n=953/953 follow-up: mean 11.4 months	oral ibopamine 100 mg three times daily versus placebo	patients with heart failure NYHA III-IV	Parallel groups double blind
Imazodan vs placebo			
IRG , 1991 n=103/44 follow-up: 3 months	Imazodan 4,10, 20 mg/d versus placebo	NYHA III,IV	Parallel groups double blind
Indolidan vs placebo			
Dies , 1989 n=38/36 follow-up: 3 months	Indolidan dose NA versus placebo	NYHA II,III	Parallel groups double blind
Milrinone vs placebo			
MMTG , 1989 n=119/111 follow-up: 3 months	Milrinone <40mg/d versus placebo	NYHA II-IV	Parallel groups double blind
PROMISE , 1991 n=561/527 follow-up: 20 months	Milrinone 40mg/d versus placebo	NYHA III,IV	Parallel groups double blind
Pimobendan vs placebo			
Bergler-Klein , 1992 n=12/12 follow-up: 6 months	Pimobendan 10mg/day versus placebo	NYHA II, III	Parallel groups double blind
PMRG , 1992 n=149/49 follow-up: 3 months	Pimobendan 2.5, 5, 10 mg/d versus placebo	NYHA III,IV	Parallel groups double blind
EPOCH , 2002 n=147/151 follow-up: 12 months	Pimobendan 2.5 to 5mg/d versus placebo	NYHA II,III	Parallel groups double blind
PICO , 1996 n=219/112 follow-up: 6 months	Pimobendan 2.5, 5 mg/d versus placebo	NYHA II, III	Parallel groups double blind
Vesnarinone vs placebo			
OPC-8212 MRG , 1990 n=45/48 follow-up: 3 months	Vesnarinone 60mg/d versus placebo	NYHA II-IV	Parallel groups double blind

continued...

Trial	Treatments	Patients	Trials design and methods
VEST , 1998 n=2550/1283 follow-up: 9 months	Vesnarinone 30, 60mg/d versus placebo	NYHA III,IV	Parallel groups double blind
VSG , 1993 n=NA follow-up: 6 months	Vesnarinone 60mg/d versus placebo	NYHA II-IV	Parallel groups double blind
enoximone vs placebo (on top metoprolol)			
EMPOWER <i>ongoing</i> [NCT00077948] n=NA follow-up:	enoximone versus placebo	Advanced CHF Subjects Previously Intolerant to Beta-Blocker Treatment	Parallel groups double blind

References

AMTG, 1985:

Massie B, Bourassa M, DiBianco R, Hess M, Konstam M, Likoff M, Packer M Long-term oral administration of amrinone for congestive heart failure: lack of efficacy in a multicenter controlled trial. *Circulation* 1985 May;71:963-71 [[3886191](#)]

EMOTE, 2007:

Feldman AM, Oren RM, Abraham WT, Boehmer JP, Carson PE, Eichhorn E, Gilbert EM, Kao A, Leier CV, Lowes BD, Mathier MA, McGrew FA, Metra M, Zisman LS, Shakar SF, Krueger SK, Robertson AD, White BG, Gerber MJ, Wold GE, Bristow MR Low-dose oral enoximone enhances the ability to wean patients with ultra-advanced heart failure from intravenous inotropic support: results of the oral enoximone in intravenous inotrope-dependent subjects trial. *Am Heart J* 2007 Nov;154:861-9 [[17967591](#)]

Cowley, 1994:

Cowley AJ, Skene AM Treatment of severe heart failure: quantity or quality of life? A trial of enoximone. *Enoximone Investigators. Br Heart J* 1994 Sep;72:226-30 [[7946771](#)]

EMTG, 1990:

Uretsky BF, Jessup M, Konstam MA, Dec GW, Leier CV, Benotti J, Murali S, Herrmann HC, Sandberg JA Multicenter trial of oral enoximone in patients with moderate to moderately severe congestive heart failure. Lack of benefit compared with placebo. *Enoximone Multicenter Trial Group. Circulation* 1990 Sep;82:774-80 [[2144216](#)]

ESG, 2000:

Lowes BD, Higginbotham M, Petrovich L, DeWood MA, Greenberg MA, Rahko PS, Dec GW, LeJemtel TH, Roden RL, Schleman MM, Robertson AD, Gorczynski RJ, Bristow MR Low-dose enoximone improves exercise capacity in chronic heart failure. *Enoximone Study Group. J Am Coll Cardiol* 2000;36:501-8 [[10933364](#)]

ESSENTIAL (I and II), 2009:

Metra M, Eichhorn E, Abraham WT, Linseman J, Bhm M, Corbalan R, DeMets D, De Marco T, Elkayam U, Gerber M, Komajda M, Liu P, Mareev V, Perrone SV, Poole-Wilson P, Roecker E, Stewart J, Swedberg K, Tendera M, Wiens B, Bristow MR Effects of low-dose oral enoximone administration on mortality, morbidity, and exercise capacity in patients with advanced heart failure: the randomized, double-blind, placebo-controlled, parallel group ESSENTIAL trials. *Eur Heart J* 2009 Dec;30:3015-26 [[19700774](#)]

Lardoux, 1987:

Lardoux H, Trimarco B, Granier G, Marcadet O, Dubois-Rande JL, Multicentric, double blind and controlled study of oral enoximone (MDL 17043) in chronic heart failure. *Circulation* 1987;76(suppl IV):IV-179(abstr 0711).2

WESG, 1991:

REFLECT II, 1991:

Cowley, 1993:

FACET, 1993:

REFLECT, 1993:

PRIME II, 1997:

IRG, 1991:
Dies, 1989:
MMTG, 1989:
PROMISE, 1991:
Bergler-Klein, 1992:
PMRG, 1992:
EPOCH, 2002:
PICO, 1996:
OPC-8212 MRG, 1990:
VEST, 1998:
VSG, 1993:
EMPOWER, :

Entry terms: Enoximone, Fenoximone, Perfan, MDL 19438, MDL-17043, MDL 17043, MDL17043, , enoximone sulfoxide, MDL 17043 sulfoxide,

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.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.