Clinical trials of endothelin receptor antagonist for acute heart failure in all type of patients

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1 endothelin receptor antagonist

Trial	Treatments	Patients	Trials design and methods
tezosentan vs			
VERITAS 1 *ongoing* [NCT00525707] n=NA follow-up:	-	-	
VERITAS 2 *ongoing* [NCT00524433] n=NA follow-up:	-	-	
tezosentan vs placebo			
RITZ 4 import , 2003 n=193 follow-up: 72h	tezosentan (25 mg/h for 1 h, then 50 mg/h for 23 to 47 h) versus placebo	patients with acute heart failure associated with acute coronary syndrome	Parallel groups double-blind
RITZ-5 , 2003 n=84 follow-up: 24h	tezosentan (50 or 100 mg/h) for up to 24 h versus placebo	patients with acute congestive heart failure	Parallel groups double-blind
VERITAS I , 2006 [NCT00525707] n=730/718 follow-up: 7 days	Infusion of tezosentan (5 mg/h for 30 minutes, followed by 1 mg/h for 24 to 72 hours versus placebo	patients with acute heart failure	Parallel groups double-blind Australia, Europe, Israel, and North America.
VERITAS II , 2007 [NCT00525707] n=730/718 follow-up: 7 days	Tezosentan versus placebo	patients with acute heart failure admitted within the previous 24 hours with persisting dyspnea and a respiratory rate of 24/min or greater	Parallel groups double-blind Australia, Europe, Israel, and North America

References

VERITAS 1, 0:

VERITAS 2, 0:

RITZ 4 import, 2003:

O'Connor CM, Gattis WA, Adams KF Jr, Shah MR, Kobrin I, Frey A, Gheorghiade M Tezosentan in patients with acute heart failure and acute coronary syndromes: design of the Randomized Intravenous Tezosentan study (RITZ-4). Am Heart J 2002;144:583-8 [12360152]

O'Connor CM, Gattis WA, Adams KF Jr, Hasselblad V, Chandler B, Frey A, Kobrin I, Rainisio M, Shah MR, Teerlink J, Gheorghiade M Tezosentan in patients with acute heart

failure and acute coronary syndromes: results of the Randomized Intravenous TeZosentan Study (RITZ-4). J Am Coll Cardiol 2003;41:1452-7 [12742280]

O'Connor CM, Gattis WA, Adams KF Jr, Shah MR, Kobrin I, Frey A, Gheorghiade M Tezosentan in patients with acute heart failure and acute coronary syndromes: design of the Randomized Intravenous Tezosentan study (RITZ-4). Am Heart J 2002;144:583-8 [12360152]

RITZ-5, 2003:

Kaluski E, Kobrin I, Zimlichman R, Marmor A, Krakov O, Milo O, Frey A, Kaplan S, Krakover R, Caspi A, Vered Z, Cotter G RITZ-5: randomized intravenous TeZosentan (an endothelin-A/B antagonist) for the treatment of pulmonary edema: a prospective, multicenter, double-blind, placebo-controlled study. J Am Coll Cardiol 2003;41:204-10 [12535809]

VERITAS I, 2006:

McMurray JJ, Teerlink JR, Cotter G, Bourge RC, Cleland JG, Jondeau G, Krum H, Metra M, O'Connor CM, Parker JD, Torre-Amione G, van Veldhuisen DJ, Lewsey J, Frey A, Rainisio M, Kobrin I Effects of tezosentan on symptoms and clinical outcomes in patients with acute heart failure: the VERITAS randomized controlled trials. JAMA 2007;298:2009-19 [17986694]

VERITAS II, 2007:

McMurray JJ, Teerlink JR, Cotter G, Bourge RC, Cleland JG, Jondeau G, Krum H, Metra M, O'Connor CM, Parker JD, Torre-Amione G, van Veldhuisen DJ, Lewsey J, Frey A, Rainisio M, Kobrin I Effects of tezosentan on symptoms and clinical outcomes in patients with acute heart failure: the VERITAS randomized controlled trials. JAMA 2007;298:2009-19 [17986694]

2 human B-type natriuretic peptide

Trial	Treatments	Patients	Trials design and methods
nesiritide vs control			
NSGET (comparative trial) , 2000 n=203/102 follow-up: <5 days	nesiritide(0.015 and 0.030 microg/kg/min versus usual care	acutely decompensated heart failure requiring invasive monitoring	Parallel groups open US
nesiritide vs placebo			
ASCEND-HF , 2011 *unpublished* [NCT00475852] n=3496/3511 follow-up: 30 days	intravenous nesiritide for 24 hours to 7 days on top of standard therapy versus matching placebo	Patients hospitalized for heart failure (within 24 hours of hospitalization and institution of acute IV therapy for ADHF)	Parallel groups double-blind North America, Europe, Latin America, Asia-Pacific region
BNP-CARDS , 2007 [NCT00186329] n=39/36 follow-up: 7 days	nesiritide as a 0.01-g/kg/min infusion for 48 hours versus placebo	acute decompensated heart failure with moderate to severe renal insufficiency	Parallel groups Double blind US
FUSION 2 , 2008 [NCT00091520] n=911 follow-up: 12 weeks	nesiritide (2 g/kg bolus plus 0.01 g/kg-per-minute infusion for four to six hours) versus placebo	patients with ACC/AHA stage C/D heart failure with two recent heart-failure hospitalizations, an ejection fraction of less than 40% , and NYHA class 4 symptoms or NYHA class 3 symptoms with creatinine clearance less than 60 mL/min	Parallel groups double-blind
NSGET (efficacy trial) , 2000 n=85/42 follow-up:	nesiritide(0.015 and 0.030 microg/kg/min versus placebo	acutely decompensated heart failure requiring invasive monitoring	

continued...

Trial	Treatments	Patients	Trials design and methods
PROACTION , 2003 n=127/123 follow-up: 30 days	nesiritidefor at least 12h versus placebo	patients presenting to the ED with acutely decompensated HF and dyspnea at rest or with minimal activity	Parallel groups double-blind USA
VMAC (intravenous neseritide) , 2002 [NCT00083772] n=204/142 follow-up:	intravenous nesiritidefor 3 hours versus placebo	acutely decompensated heart failure requiring hospitalization	double-blind USA
nesiritide vs dobutamine			
PRECEDENT , 2002 [NCT00270400] n=NA follow-up:	nesiritide(0.015 or 0.03 microg/kg/min) versus Dobutamine (>or =5 microg/kg/min)	Symptomatic, Decompensated CHF	Parallel groups open
nesiritide vs nitroglycerin			
VMAC (24h) , 2002 [NCT00083772] n=280/218 follow-up:	nesiritideinfusion for 24 hours versus nitroglycerin	acutely decompensated heart failure requiring hospitalization	
nesiritide vs standard care			
FUSION 1 , 2004 [NCT00270361] n=NA follow-up: 12 weeks	nesiritide 0.005 microg/kg/min or 0.010 microg/kg/min once weekly versus standard care	outpatient with co-morbid advanced heart failure and renal insufficiency	Parallel groups open

References

NSGET (comparative trial), 2000:
ASCEND-HF, 2011:
BNP-CARDS, 2007:
FUSION 2, 2008:
NSGET (efficacy trial), 2000:
PROACTION, 2003:
VMAC (intravenous neseritide), 2002:
PRECEDENT, 2002:
VMAC (24h), 2002:
FUSION 1, 2004:

3 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.