Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Pfeffer MA, McMurray JJV, Velazquez EJ, et al. Valsartan, Captopril, or Both in Myocardial Infarction Complicated by Heart Failure, Left Ventricular Dysfunction, or Both. N Engl J Med 2003;349:1893-906.

Supplementary Appendix 1. Definition of End Points.

End Point	Definition
Reinfarction	An increase in cardiac enzymes as follows: Both total creatine kinase and creatine kinase-MB levels above the upper limit of normal with the level of at least one enzyme at least twice the upper limit of normal Creatine kinase-MB level elevated to at least twice the upper limit of normal when total creatine kinase level was unavailable or to above the upper limit of normal if confirmed by troponin T or I level at least three times the upper limit of normal Total creatine kinase level elevated to at least twice the upper limit of normal when creatine kinase-MB level was unavailable or to above the upper limit of normal if confirmed by troponin T or I level at least three times the upper limit of normal Troponin T or I level at least five times the upper limit of normal if neither total creatine kinase level nor creatine kinase-MB level was available Patients also had to meet one of the following electrocardiographic criteria for reinfarction: typical clinical presentation consistent with infarction; typical electrocardiographic changes in two or more contiguous leads — new Q or QS waves or new R waves in V_1 or V_2; new left bundle-branch block, or evolving ischemic ST-segment or T-wave changes
Periprocedural infarction	Infarction during or after angioplasty or stent implantation involving a creatine kinase or creatine kinase-MB level at least three times the upper limit of normal; in addition, either the typical clinical presentation consistent with infarction or the electrocardiographic changes described above
Postsurgical myocardial infarction	Infarction occurring after a coronary bypass procedure if new Q waves were present and the creatine kinase level was elevated to at least five times the upper limit of normal and the creatine kinase-MB value was at least 5 percent of the total creatine kinase value
Congestive heart failure	An unplanned presentation for new or worsening heart failure requiring an overnight stay or admission to any health care facility in which the patient received intravenous treatment with inotropic, diuretic, or vasodilator therapy
Sudden cardiac arrest with resuscitation	Sudden cardiac arrest, with or without premonitory heart failure or infarction, followed by resuscitation by means of cardioversion, defibrillation, or cardiopulmonary resuscitation, with a regaining of cognitive function; excludes patients with known transient loss of consciousness, such as those who had a seizure or vasovagal episode, that did not reflect clinically significant cardiac dysfunction
Stroke	A focal neurologic deficit lasting more than 24 hours or resulting in death that was presumed to be related to stroke
Rehospitalization	Any admission to the hospital; the primary reason for hospitalization was classified in 1 of 32 categories
Death from cardiovascular causes	
Sudden death	Death that occurred suddenly and unexpectedly in which the time of death was known; further classified as follows: witnessed deaths due to an identified arrhythmia (identified on electrocardiographic or monitor recording or witnessed by a medic or a paramedic); cardiac arrest, cardiovascular collapse without premonitory heart failure or infarction, or other mode of death; death during or after successful resuscitation from sudden cardiac arrest; or unwitnessed deaths, which included those for which the time of death was unknown but the patient has been seen within the previous 24 hours
Presumed cardiovascular death	Death occurring within 24 hours after the patient's last visit and presumed to be sudden
Fatal pump failure	Death occurring after new or worsening symptoms or signs of heart failure; patients being treated for heart failure who had sudden death as the terminal event were classified as having a pump-failure–related death: heart failure with secondary arrhythmic death or heart failure without secondary arrhythmic death
Fatal reinfarction	Death occurring after a recorded infarction without conclusive evidence of another cause of death; or death with evidence on autopsy of recent infarction without other conclusive evidence of another cause of death; or abrupt death with criteria suggestive of an infarct but that does not meet the strict definition of infarction — suggestive criteria include chest pain plus one of the following: electrocardiographic changes indicative of infarction, abnormal markers without evolutional changes (i.e., patient died before later samples could be obtained), or other evidence of new wall-motion abnormality
Cardiovascular-procedure–related death	Death occurring during a cardiovascular procedure (bypass surgery, angioplasty, or other) or as a result of events related to the procedure
Stroke-related death	Death occurring after a recorded stroke
Death from other cardiovascular causes	Death from a recorded cardiovascular cause not included above
Death from noncardiovascular causes	Death with an unequivocal and recorded noncardiovascular cause
Death from unknown causes	Any death that did not fall into the above categories

Supplementary Appendix 2. Definitions of Adverse Events.*

Type of Event	Events Included
Hypotension	Hypotension, orthostatic hypotension, decreased blood pressure, decreased systolic blood pressure, aggravated hypotension
Renal cause	Increased blood creatinine level, renal failure, acute renal failure, renal impairment, azotemia, progressive renal failure, aggravated renal failure, chronic aggravated renal failure, chronic renal failure, acute prerenal failure, renal tubular necrosis, anuria
Hyperkalemia	Hyperkalemia, increased blood potassium level
Cough	
Rash	Rash, allergic dermatitis, macular rash, maculopapular rash, pruritic rash, skin reaction, urticaria, pruritus, generalized rash
Taste disturbances	Dysgeusia, ageusia, hypogeusia
Angioedema	Anaphylactic reaction, anaphylactic shock, laryngeal edema, angioneurotic edema, swollen tongue, throat tightness

* These types of adverse events are common with drugs affecting the renin–angiotensin system; in some patients, they led to the reduction of the dose of the study drug or the discontinuation of study treatment. Increased blood creatinine levels and hyperkalemia were investigator-reported events and were not defined in terms of specific biochemical values.