

# Case Report Form



FONDAZIONE I.R.C.A.B.

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CRF1 Patient ID

CRF2 Name and surname \_\_\_\_\_

CRF3 Gender  M  F

CRF4 Date of birth  <sup>dd</sup>  <sup>mm</sup>  <sup>yy</sup>

CRF5 Age  yrs

CRF6 Admission date  <sup>dd</sup>  <sup>mm</sup>

CRF7 Time  <sup>hrs</sup>

## History

- CRF8 Known CAD  Y  N
- CRF10 Unstable Angina  Y  N
- CRF12 Myocardial Infarction  Y  N
- CRF14 Coronary Angiography  Y  N
- CRF16 Coronary Angioplasty  Y  N
- CRF18 Bypass Surgery  Y  N

## Risk factors

- CRF9 Hypertension <sup>1</sup>  Y  N
- CRF11 Smoker <sup>2</sup>  Y  N
- CRF13 Diabetes mellitus  Y  N
- CRF15 CAD in family <sup>3</sup>  Y  N
- CRF17 Hypercholesterolemia <sup>4</sup>  Y  N

## Medications used before admission

- CRF19 No cardiac medication  Y  N
- CRF20 B-adrenergic blockers  Y  N
- CRF21 Calcium Antagonist  Y  N
- CRF22 Nitrates  Y  N
- CRF23 Oral Anticoagulants  Y  N
- CRF24 Antiplatelet aggregating agents  Y  N
- CRF25 Other (specify) \_\_\_\_\_  Y  N

CRF26 Last Pain Attach:  0-3 hours  3-6 hours  6-12 hours  12-24 hours

CRF27 Quality of pain:  Sharp  Burning  Tightness  Dull  
 Pressure  Stabbing  Atypical

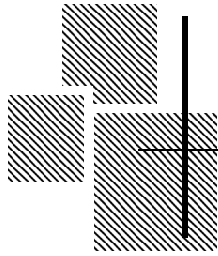
CRF28 Location of Pain:  Back  Left Arm  Right Arm  Both Arms  
 Substernal  Epigastrium

<sup>1</sup> BP > 160/90 mm Hg or current antihypertensive treatment

<sup>2</sup> Until less than 6 months ago

<sup>3</sup> Myocardial infarction or sudden death before 55 years at age in parents or siblings

<sup>4</sup> LDL colessterol > 130 mg/dl or current antilipemia treatment



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## ADMISSION DATA

CRF29 Pain at admission  Y  N

### Physical Examination

CRF30/31 Blood Pressure  /  mm Hg

CRF32 Heart Rate  beats/min

CRF33 The patient is sweating  Y  N

CRF34 ECG t=0 hours (Exact Time)  hrs  min

CRF35 QRS Complex:  Normal  LVH  LBB  RBB  
 Acute Myocardial Infarction

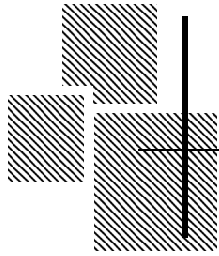
CRF36 ST-T segment:  Normal  Non specific ST-T changes  Ischemic ST-changes

CRF37 Abnormalities at chest X-ray  Y  N

	Value	Conclusion	Type of test
CRF38/39/40/40b	Troponine I <input type="text"/> , <input type="text"/>	<input type="radio"/> Positive <input type="radio"/> Negative	<input type="radio"/> Quantitative <small>specify</small> _____ <input type="radio"/> Qualitative
CRF41/42/43/43b	Troponine T <input type="text"/> , <input type="text"/>	<input type="radio"/> Positive <input type="radio"/> Negative	<input type="radio"/> Quantitative <small>specify</small> _____ <input type="radio"/> Qualitative
CRF44/45/46/46b	Myoglobine <input type="text"/> , <input type="text"/>	<input type="radio"/> Positive <input type="radio"/> Negative	<input type="radio"/> Quantitative <small>specify</small> _____ <input type="radio"/> Qualitative
CRF47/48/49/49b	CK-MB <input type="text"/>	<input type="radio"/> Positive <input type="radio"/> Negative	<input type="radio"/> Activity (ul/L) <small>specify</small> _____ <input type="radio"/> Mass (mg/ml)
CRF50/51	Total CK <input type="text"/>	<input type="radio"/> Positive <input type="radio"/> Negative	

CRF52 Enzymes determination (Exact Time)  hrs

CRF53 Conclusion (from CK or Troponine)  Positive  Negative for Acute Cardiac Damage



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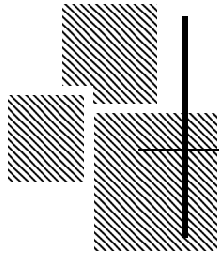
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*Observational Period between Admission and Randomization (within 6 hrs since pain)*

**Medications administered during Observation**

CRF54	No therapy	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF55	Calcium antagonists	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF56	Oral Nitrates	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF57	Anticoagulants	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF58	Intravenous Nitrates	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF59	Antiplatelet aggregating agents	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF60	B-adrenergic blockers	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF61	Heparin	<input type="checkbox"/> Y <input type="checkbox"/> N
CRF62	Hospitalization for chest pain		Date	<input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value=""/>	
CRF63	Proven new unstable angina		Date	<input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value=""/>	
CRF64	Pain during observation	<input type="checkbox"/> Y <input type="checkbox"/> N			

CRF65	ECG with pain (Exact Time)	<input type="text" value="hrs"/> <input type="text" value="min"/>
CRF66	QRS Complex:	<input type="radio"/> Normal <input type="radio"/> LVH <input type="radio"/> LBB <input type="radio"/> RBB <input type="radio"/> Acute Myocardial Infarction
CRF67	ST-T segment:	<input type="radio"/> Normal <input type="radio"/> Non specific ST-T changes <input type="radio"/> Ischemic ST-changes
CRF68	ECG with pain (Exact Time)	<input type="text" value="hrs"/> <input type="text" value="min"/>
CRF69	QRS Complex:	<input type="radio"/> Normal <input type="radio"/> LVH <input type="radio"/> LBB <input type="radio"/> RBB <input type="radio"/> Acute Myocardial Infarction
CRF70	ST-T segment:	<input type="radio"/> Normal <input type="radio"/> Non specific ST-T changes <input type="radio"/> Ischemic ST-changes
CRF71	ECG with pain (Exact Time)	<input type="text" value="hrs"/> <input type="text" value="min"/>
CRF72	QRS Complex:	<input type="radio"/> Normal <input type="radio"/> LVH <input type="radio"/> LBB <input type="radio"/> RBB <input type="radio"/> Acute Myocardial Infarction
CRF73	ST-T segment:	<input type="radio"/> Normal <input type="radio"/> Non specific ST-T changes <input type="radio"/> Ischemic ST-changes



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CRF74 ECG with pain (Exact Time)  hrs  min

CRF75 QRS Complex:       Normal       LVH       LBB       RBB  
 Acute Myocardial Infarction

CRF76 ST-T segment:       Normal       Non specific ST-T changes       Ischemic ST-changes

CRF77 Total number of ECG's

### Additional procedures performed:

CRF78 Echocardiogram Transthoracic  Y  N      CRF79 nr.

CRF80 Echocardiogram Transesophageal  Y  N      CRF81 nr.

CRF82 Tc 99m Myocardial  Y  N      CRF83 nr.

CRF84 Perfusion scan  Y  N      CRF85 nr.

CRF86 Other (specify) \_\_\_\_\_

CRF87 ECG t=6 hours since pain (Exact Time)  hrs  min

CRF88 QRS Complex:       Normal       LVH       LBB       RBB  
 Acute Myocardial Infarction

CRF89 ST-T segment:       Normal       Non specific ST-T changes       Ischemic ST-changes

### Pre- Randomization evaluation

CRF90 Age < 30  Y  N

CRF91 For ischemia conclusive CK enzymes and/or Troponine Test positive  Y  N

CRF92 For ischemia conclusive ECG changes  Y  N

CRF93 Events during observational period  Y  N

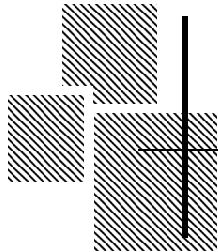
CRF94 No informed consent given  Y  N

If you answered YES to ANY of the previous questions, DO NOT proceed further and send the Randomization Performed Form to the ASSENCE Monitoring Comitee

Otherwise, proceed with randomization according to the Randomization List and send the Randomization Performed Form to the ASSENCE Monitoring Comitee

CRF95 NHP submitted  Y  N

CRF96 **Randomized to strategy :**     Conventional Observational Period (go to page 7)  
 DASE (go to page 5)       EET (go to page 6)



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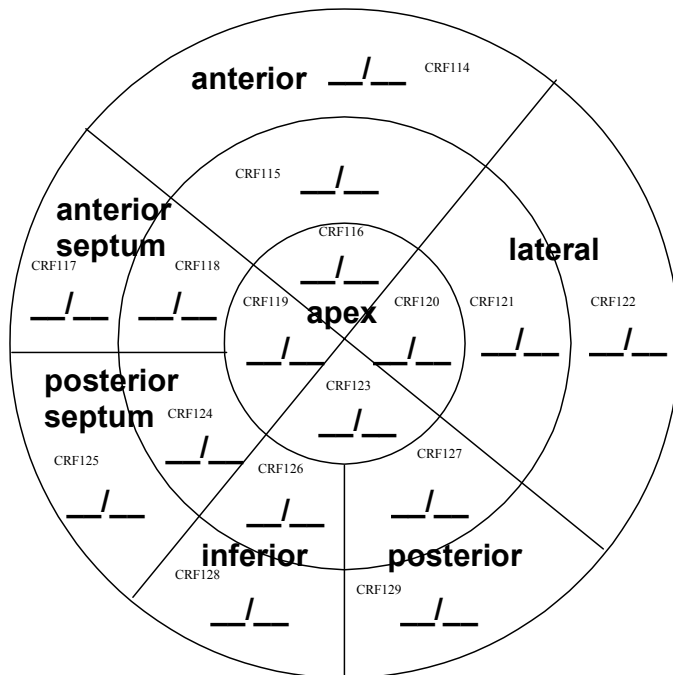


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## DOBUTAMINE ATROPINE STRESS ECHOCARDIOGRAPHY

- CRF97 Dobutamine Atropine Stress Echocardiography (DASE) performed  Y  N
- CRF98 If not Why?  Insufficient Acoustic Window  Organizational problems
- CRF99 Date  <sup>dd</sup>  <sup>mm</sup>  CRF100 Time  <sup>hrs</sup>  <sup>min</sup>
- CRF101 Basal Heart rate  /  beats/min
- CRF102/103 Basal BP  /  mm Hg
- CRF104 Dobutamine Dose  mcg/Kg/min
- CRF105 Atropine Dose  ,  mg
- CRF106 Peak Heart Rate  /  beats/min
- CRF107/108 Peak BP  /  mm Hg
- CRF109 Angina  Y  N
- CRF110 Arrhythmias  Y  N
- CRF111 Wall Motion Abnormalities  Y  N
- CRF112 Side Effects (nausea, ...)  Y  N
- CRF113 Conclusions  Inducible ischemia  no inducible ischemia

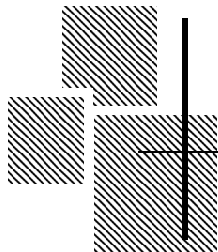


### WALL MOTION SCORE

- 1 = normal
- 2 = hypokinetic
- 3 = akinetic
- 4 = diskintetic

rest / stress  /  CRF130

- CRF131 Patient discharge  Y  N
- If YES
- CRF132 Discharge Date  <sup>dd</sup>  <sup>mm</sup>  CRF133 Time  <sup>hrs</sup>  <sup>min</sup>



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***ELECTROCARDIOGRAPHIC EXERCISE TEST***

CRF134 Exercise ECG performed  Y  N

CRF135 If not Why?  Patient unable to exercise  Organizational problems

CRF136 Date <sup>dd</sup> <sup>mm</sup>  CRF137 Time <sup>hrs</sup> <sup>min</sup>

CRF138 Rest Heart Rate   beats/min

CRF139/140 Rest BP  /  mm Hg

CRF141 Peak Heart Rate   beats/min

CRF142/143 Peak basal BP  /  mm Hg

CRF144 Workload   Watts

CRF145 ST-T Segment Changes  Y  N

CRF146 Angina  Y  N

CRF147 Ischemia response  Y  N

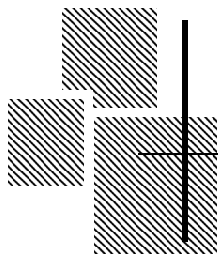
CRF148 Not Ischemia response  Y  N

CRF149 Inconclusive  Y  N

CRF150 Patient discharge  Y  N

If YES

CRF151 Discharge Date <sup>dd</sup> <sup>mm</sup>  CRF152 Time <sup>hrs</sup> <sup>min</sup>



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## CONVENTIONAL OBSERVATIONAL PERIOD

Additional procedures performed:

CRF153	Echocardiogram Transthoracic	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF154	nr.	<input type="checkbox"/>
CRF155	Echocardiogram Transesophageal	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF156	nr.	<input type="checkbox"/>
CRF157	Tc 99m Myocardial	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF158	nr.	<input type="checkbox"/>
CRF159	Perfusion scan	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF160	nr.	<input type="checkbox"/>
CRF161	Exercise Electrocardiographic Test	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF162	nr.	<input type="checkbox"/>
CRF163	Stress Echocardiography	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF164	nr.	<input type="checkbox"/>
CRF165	Coronary Angiography	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF166	nr.	<input type="checkbox"/>
CRF167	Other (specify) _____				<input type="checkbox"/>

## Events During Hospitalization

CRF168	Coronary angioplasty	Date	<input type="checkbox"/> <input type="checkbox"/> <sup>dd</sup>	<input type="checkbox"/> <input type="checkbox"/> <sup>mm</sup>	<input type="checkbox"/> <input type="checkbox"/>
CRF169	Bypass Surgery	Date	<input type="checkbox"/> <input type="checkbox"/> <sup>dd</sup>	<input type="checkbox"/> <input type="checkbox"/> <sup>mm</sup>	<input type="checkbox"/> <input type="checkbox"/>
CRF170	Myocardial Infarction	Date	<input type="checkbox"/> <input type="checkbox"/> <sup>dd</sup>	<input type="checkbox"/> <input type="checkbox"/> <sup>mm</sup>	<input type="checkbox"/> <input type="checkbox"/>
CRF171	Cardiac Death	Date	<input type="checkbox"/> <input type="checkbox"/> <sup>dd</sup>	<input type="checkbox"/> <input type="checkbox"/> <sup>mm</sup>	<input type="checkbox"/> <input type="checkbox"/>
CRF172	Non-Cardiac Death	Date	<input type="checkbox"/> <input type="checkbox"/> <sup>dd</sup>	<input type="checkbox"/> <input type="checkbox"/> <sup>mm</sup>	<input type="checkbox"/> <input type="checkbox"/>
CRF173	Other (specify) _____	Date	<input type="checkbox"/> <input type="checkbox"/> <sup>dd</sup>	<input type="checkbox"/> <input type="checkbox"/> <sup>mm</sup>	<input type="checkbox"/> <input type="checkbox"/>

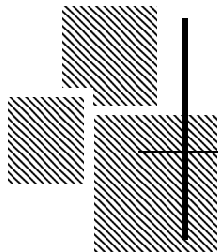
CRF174 Coronary Angiography performed  Y  N

CRF175  No CAD  1V disease  2V disease  3V disease  LM

CRF176 Discharge Date   <sup>dd</sup>   <sup>mm</sup>   <sup>CRF177</sup> Time   <sup>hrs</sup>   <sup>min</sup>

CRF178 Discharge diagnosis  Myocardial infarction  Ischemic Chest Pain  
 Non ischemic chest pain

CRF179 Diagnosis made by  Stress Echo  Exercise ECG  CAG  Clinical data



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## FOLLOW-UP

Additional procedures or events to record on follow-up forms does not include procedures performed and events occurred during index hospital admission

CRF180  Date <sup>dd</sup> <sup>mm</sup>

CRF181 Follow up by  Phone  Visit  Administrative Data  Other

Additional procedures performed:

CRF182	Echocardiogram Transthoracic	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF183	nr.	<input type="text" value=""/>
CRF184	Echocardiogram Transesophageal	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF185	nr.	<input type="text" value=""/>
CRF186	Tc 99m Myocardial	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF187	nr.	<input type="text" value=""/>
CRF188	Perfusion scan	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF189	nr.	<input type="text" value=""/>
CRF190	Exercise Electrocardiographic Test	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF191	nr.	<input type="text" value=""/>
CRF192	Stress Echocardiography	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF193	nr.	<input type="text" value=""/>
CRF194	Coronary Angiography	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF195	nr.	<input type="text" value=""/>
CRF196	Other (specify) _____				<input type="text" value=""/>

CRF197 Coronary angioplasty Date <sup>dd</sup> <sup>mm</sup>

CRF198 Bypass Surgery Date <sup>dd</sup> <sup>mm</sup>

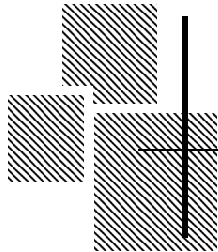
CRF199 Myocardial Infarction Date <sup>dd</sup> <sup>mm</sup>

CRF200 Cardiac Death Date <sup>dd</sup> <sup>mm</sup>

CRF201 Non-Cardiac Death Date <sup>dd</sup> <sup>mm</sup>

CRF202 Other (specify) \_\_\_\_\_ Date <sup>dd</sup> <sup>mm</sup>

CRF203 Readmission Date <sup>dd</sup> <sup>mm</sup>  CRF204 Time <sup>hrs</sup> <sup>min</sup>



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***FOLLOW-UP***

Additional procedures or events to record on follow-up forms does not include procedures performed and events occurred during index hospital admission

CRF205  Date

CRF206 Follow up by  Phone  Visit  Administrative Data  Other

Additional procedures performed:

CRF207	Echocardiogram Transthoracic	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF208	nr.	<input type="text"/>
CRF209	Echocardiogram Transesophageal	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF210	nr.	<input type="text"/>
CRF211	Tc 99m Myocardial	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF212	nr.	<input type="text"/>
CRF213	Perfusion scan	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF214	nr.	<input type="text"/>
CRF215	Exercise Electrocardiographic Test	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF216	nr.	<input type="text"/>
CRF217	Stress Echocardiography	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF218	nr.	<input type="text"/>
CRF219	Coronary Angiography	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF220	nr.	<input type="text"/>
CRF221	Other (specify) _____				<input type="text"/>

CRF222 Coronary angioplasty Date

CRF223 Bypass Surgery Date

CRF224 Myocardial Infarction Date

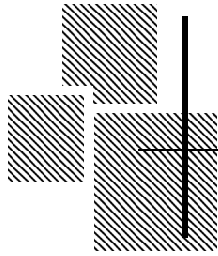
CRF225 Cardiac Death Date

CRF226 Non-Cardiac Death Date

CRF227 Other (specify) \_\_\_\_\_ Date

CRF228 Readmission 1 Date    CRF229 Time

CRF230 Readmission 2 Date    CRF231 Time



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**FOLLOW-UP**

Additional procedures or events to record on follow-up forms does not include procedures performed and events occurred during index hospital admission

CRF232  Date

CRF233 Follow up by  Phone  Visit  Administrative Data  Other

Additional procedures performed:

CRF234	Echocardiogram Transthoracic	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF235	nr.	<input type="text"/>
CRF236	Echocardiogram Transesophageal	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF237	nr.	<input type="text"/>
CRF238	Tc 99m Myocardial	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF239	nr.	<input type="text"/>
CRF240	Perfusion scan	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF241	nr.	<input type="text"/>
CRF242	Exercise Electrocardiographic Test	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF243	nr.	<input type="text"/>
CRF244	Stress Echocardiography	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF245	nr.	<input type="text"/>
CRF246	Coronary Angiography	<input type="checkbox"/> Y <input type="checkbox"/> N	CRF247	nr.	<input type="text"/>
CRF248	Other (specify) _____				<input type="text"/>

CRF249 Coronary angioplasty Date

CRF250 Bypass Surgery Date

CRF251 Myocardial Infarction Date

CRF252 Cardiac Death Date

CRF253 Non-Cardiac Death Date

CRF254 Other (specify) \_\_\_\_\_ Date

CRF255 Readmission 1 Date    CRF256 Time

CRF257 Readmission 2 Date    CRF258 Time