

COURAGE Protocol Amendment

7/19/1999

Some of the windows specified in the protocol seem to be creating artificial barriers to enrollment, specifically the days for catheterization and PCI procedure seem overly restrictive.

The NEW study policy will be

1. The angiogram should have been done no longer than 90 days prior to randomization.
2. The PCI should be performed no longer than 105 days after the diagnostic angiogram.
3. Although no limits were described for documentation of ischemia in the protocol, the study policy will also be that this documentation should take place within 90 days of randomization.

All of these limits are subject to the restriction that

- a. There has been no intercurrent event.
- b. The patient is stable and has had no worsening of symptoms since the test was performed.

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