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LETTERS

PATIENTS AND TRIAL ENROLMENT DECISIONS

Flexibility in trial enrolment decisions

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We read the debate about patient consent in acute myocardial infarction trials with interest.[1]

We randomly allocated critically ill patients with an admission diagnosis of ruptured abdominal aortic aneurysm to endovascular repair or open surgical repair.[2] Of the 652 patients approached for initial brief consent, 42 (6.4%) refused because they had a preference for no treatment or for a specific treatment. Six hundred and thirteen patients were randomised, 509 (83%) of whom provided brief witnessed verbal or written consent. A relative or carer provided consent for 44 (7%), and 60 (10%) were randomised using the Mental Capacity Act, with a clinician from outside the immediate management team confirming that this route was appropriate. For patients who survived until discharge, further full consent was obtained, and at this point 6/384 (2%) patients refused consent.

It seems important to allow patients the option of immediate consent whenever possible (in our experience nearly all agree to participate) and to allow them to reconsider this decision when their health has improved. This type of flexible arrangement could also be used in acute myocardial infarction trials.

Competing interests: None declared.

1 Dickert NW, Miller FG. Involving patients in enrolment decisions for acute myocardial infarction trials. *BMJ* 2015;351:h3791. (29 July.)
2 IMPROVE Trial Investigators. Endovascular or open repair strategy for ruptured abdominal aortic aneurysm: 30 day outcomes from IMPROVE randomised trial. *BMJ* 2014;348:f7661.

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