Amaze: a double-blind, multicentre randomised controlled trial to investigate the clinical effectiveness and cost-effectiveness of adding an ablation device-based maze procedure as an adjunct to routine cardiac surgery for patients with pre-existing atrial fibrillation

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Plain English summary

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Irregular heartbeat is common, and the most common type is atrial fibrillation (AF). The heart has four chambers: two ventricles that propel blood from the heart and two atria that receive blood. In AF, the chambers of the heart lose their pumping action and the heart becomes less efficient. Blood can settle in the atria and form clots. These can detach and cause strokes, so AF patients are given blood-thinning drugs to reduce this risk. These drugs can increase the risk of bleeding. The maze procedure is an operation designed to stop AF and make the heart beat regularly again.

Many patients who need major heart surgery also have AF. The Amaze trial was designed to find out whether or not adding a maze procedure to heart operations is useful in making the heartbeat regular again, if it improves long-term survival and quality of life (QoL) and whether or not any benefits are worth the extra costs.

Between 25 February 2009 and 6 March 2014, 352 patients in 11 hospitals were recruited and randomly put into one of two treatment groups: (1) maze and planned heart surgery or (2) planned surgery alone. The results showed that patients in the maze group were more likely to have a normal, regular heartbeat afterwards; however, there were no differences in survival or QoL at 2 years. In addition, many maze patients who recovered a regular heartbeat did well in terms of the heart's pumping action, suggesting that longer follow-up may show better QoL and survival in these patients.

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