

First trial restored under new initiative casts doubt on repeat bowel cancer surgery

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A trial that remained unpublished for 20 years casts doubt on the survival benefit of repeat—'second look'—surgery for bowel cancer.

The trial is published in the online journal *BMJ Open* today. It is the first to be restored under the restoring invisible and abandoned <u>trials</u> (RIAT) initiative that allows third parties to publish previously abandoned studies when the original researchers or sponsors fail to do so.

The initiative was announced last year by editors of *The BMJ* and *PLOS Medicine* as a way to complete and correct the scientific record, so that doctors and patients have access to accurate information to make decisions about treatments.

On <u>bmj.com</u> today, Professor Tom Treasure and colleagues tell the story behind the trial and discuss what it means today.

The trial started in 1982 and examined the use of a tumour marker (carcinoembryonic antigen or CEA) to detect cancer recurrence early and prompt second look surgery. The researchers wanted to see whether this would result in better survival.

Nearly 1,500 <u>bowel cancer</u> patients who had already had surgery took part in the trial. Those with high CEA levels, suggesting their cancer had returned, were randomised to further surgery (active arm) or to continued review (control arm).



But the trial was stopped early in 1993 when it was found that there were more deaths in the active arm than the control arm.

Although there was a clear intention to publish the results, various factors led to the trial team breaking up and the data were thought to be irretrievably lost.

When the RIAT initiative was announced, Professor Tom Treasure at University College London and colleagues at the University of Sussex and Imperial College London had already retrieved the archived files and were in the process of analysing the data.

Spurred on by the initiative, their updated analysis confirms that there is no hint of a survival advantage associated with knowledge of the CEA.

They acknowledge that methods of detection, imaging, and surgical resection have changed over the intervening 20 years, but they do not believe that the findings can be readily discounted.

They say the new evidence "should fuel uncertainty about present day second look <u>surgery</u> for colorectal <u>cancer</u> in its various forms and hope that it will give some encouragement to undertake the randomised trials that are needed."

Provided by British Medical Journal

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