An international randomised controlled trial to compare TARGeted Intraoperative radioTherapy (TARGIT) with conventional postoperative radiotherapy after breast-conserving surgery for women with early-stage breast cancer (the TARGIT-A trial)

Jayant S Vaidya,¹,²* Frederik Wenz,³ Max Bulsara,⁴ Jeffrey S Tobias,⁵ David J Joseph,⁶ Christobel Saunders,⁷ Chris Brew-Graves,¹ Ingrid Potyka,¹ Stephen Morris,⁸ Hrisheekesh J Vaidya,⁹ Norman R Williams¹ and Michael Baum¹

¹Division of Surgery and Interventional Science, University College London, London, UK
²Department of Surgery, Whittington Hospital, Royal Free Hospital and University College London Hospital, London, UK
³Department of Radiation Oncology, University Medical Centre Mannheim, University of Heidelberg, Heidelberg, Germany
⁴Department of Biostatistics, University of Notre Dame, Fremantle, WA, Australia
⁵Department of Clinical Oncology, University College London Hospitals, London, UK
⁶Department of Radiation Oncology, Sir Charles Gairdner Hospital, Perth, WA, Australia
⁷Department of Surgery, University of Western Australia, Perth, WA, Australia
⁸Health Economics Group, Department of Biomedical Engineering, University College London, London, UK
⁹Keble College, Oxford University, Oxford, UK

*Corresponding author
Declared competing interests of authors: Jayant S Vaidya has received a research grant from Photoelectron Corp. (1996–9) and from Carl Zeiss for supporting data management at the University of Dundee (Dundee, UK) and has subsequently received honoraria. Jayant S Vaidya also has a patent for the use of the word TARGIT for TARGeted Intraoperative radioTherapy. Frederik Wenz has received a research grant from Carl Zeiss for supporting radiobiological research. Frederik Wenz also has patents for US 8,724,775B2, US 2013/058460 A, PCT/EP2011/057518, DE/18.12.09/DEA10200905877 and DE/17.12.09/DEA10200905058581, all issues to Wenz/Zeiss. Chris Brew-Graves, Ingrid Potyka and Norman R Williams report that the Clinical Trials Group was paid an unrestricted grant from 1 November 2001 to 31 October 2010. Michael Baum was on the scientific advisory board of Carl Zeiss and was paid monthly consultancy fees until 2010. In addition, Jayant S Vaidya, Frederik Wenz, Max Bulsara, Jeffrey S Tobias, David J Joseph, Christobel Saunders and Michael Baum report that Carl Zeiss sponsors most of the travel and accommodation for meetings of the International Steering Committee and Data Monitoring Committee and, when necessary, for conferences where a presentation about targeted intraoperative radiotherapy is being made for all authors.

Plain English summary

The TARGIT-A trial
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About 70% of patients with breast cancer are eligible for breast-conserving surgery (a lumpectomy), after which the remaining breast is treated with radiotherapy; this avoids a full mastectomy.

Traditionally, external beam radiotherapy (EBRT) is delivered to the entire breast in small doses every day for 3–6 weeks, necessitating patients to travel to and from the radiotherapy centre every working day. This can be impractical and strenuous.

The TARGIT (TARGeted Intraoperative radioTherapy) procedure precisely delivers radiation in a single dose during the lumpectomy operation over 15–35 minutes, using a ball-shaped device that is placed in the space where the tumour was. This way, unnecessary potentially harmful radiation to healthy tissues (skin, heart, lungs, etc.) is avoided and the areas nearest to the tumour site receive the most radiation. In this way, four-fifths of patients avoid EBRT altogether.

The TARGIT-A (TARGeted Intraoperative radioTherapy Alone) trial compared TARGIT with EBRT in 3451 patients who were aged $\geq$ 45 years and found that, when TARGIT is given with lumpectomy, the control of breast cancer is much the same as with EBRT. The chances of being alive without return of cancer in the breast at 5 years were 93.9% with TARGIT during lumpectomy and 92.5% with EBRT. Compared with EBRT, TARGIT had fewer side effects and fewer deaths from heart attacks or other cancers. TARGIT would be less expensive than EBRT, potentially saving the NHS up to £9.1 million a year, without considering the cost savings to patients.

Targeted intraoperative radiotherapy during lumpectomy is an effective, safer and less expensive option for eligible patients.
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This report

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