IRMA

WHOLE- VS PARTIAL-BREAST IRRADIATION

Very low recurrence, noninferiority not shown

J Clin Oncol 2026, online November 17 · Meduri et al.

DESIGN · PHASE III, NONINFERIORITY

5-year efficacy analysis

Randomised 1:1 | **Open-label** | **Median 97.5 mo**

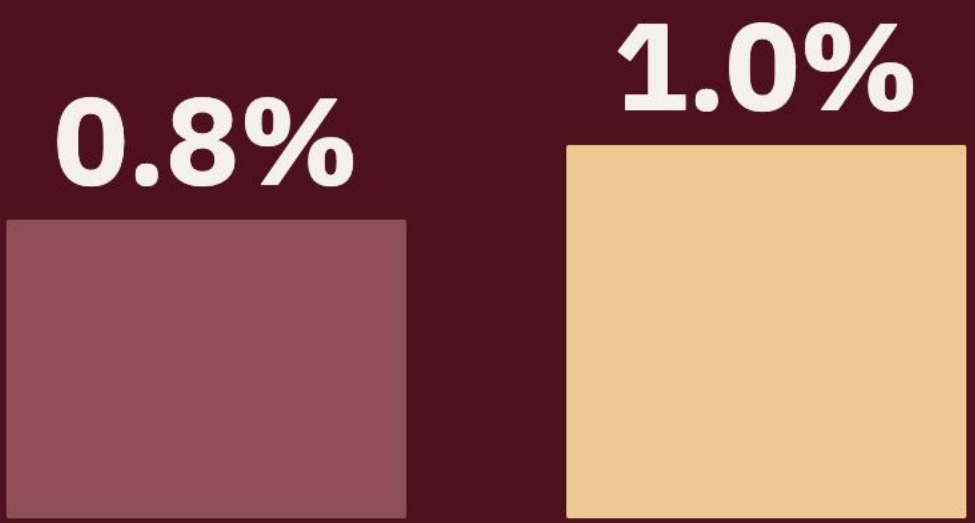
PATIENTS	3,309 randomised · age ≥49 · invasive, ≤3 cm, pN0–1
ARMS	WBI 50 Gy in 25 fractions or hypofractionated ± boost vs APBI 38.5 Gy in 10 fractions twice daily
THIS REPORT	Planned 5-year analysis of efficacy end points, modified intention to treat (1,623 vs 1,602)
PRIMARY	Ipsilateral breast tumour recurrence

WBI: whole-breast irradiation · APBI: accelerated partial-breast irradiation

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PRIMARY END POINT · CUMULATIVE INCIDENCE

Ipsilateral breast tumour recurrence at 5 years



HR 1.18 (90% CI 0.63 to 2.20), APBI vs WBI

13 vs 15 events · difference 0.15 percentage points (90% CI −0.31 to 0.99)

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NONINFERIORITY TEST · HAZARD RATIO

Noninferiority not formally demonstrated

	VALUE
Noninferiority margin	**1.5**
Observed hazard ratio Partial-breast vs whole-breast · 90% CI 0.63 to 2.20	**1.18**
Upper 90% confidence limit Above the margin of 1.5	**2.20**
Events, observed / planned	**28 / 208**

- **Assumed 5-year recurrence with whole-breast irradiation: 4%; observed: 0.8%.**
- **The prespecified test was on the hazard ratio. No P value is reported.**

SITE OF RECURRENCE · 5-YEAR INCIDENCE

Where recurrences occurred

	WBI	APBI
True or marginal recurrence (within 2 cm of the tumour bed) 10 vs 11 events · HR 1.12 (90% CI 0.55 to 2.30)	0.6%	0.7%
Elsewhere in the ipsilateral breast 3 vs 4 events · HR 1.36 (90% CI 0.39 to 4.76)	0.2%	0.3%

- The authors note limitations in identifying the site of recurrence.

WBI: whole-breast, APBI: partial-breast irradiation · HR: APBI vs WBI

SECONDARY END POINTS · 5 YEARS

Other efficacy end points

	WBI	APBI
Overall survival HR for death 0.80 (90% CI 0.56 to 1.15)	97.0%	97.6%
Disease-free survival HR 0.97 (90% CI 0.73 to 1.26)	95.2%	95.4%
Regional recurrence HR 0.87 (90% CI 0.35 to 2.17)	0.4%	0.4%
Distant recurrence HR 1.07 (90% CI 0.65 to 1.76)	1.3%	1.4%

- No P values reported; not adjusted for multiplicity.

WBI: whole-breast, APBI: partial-breast irradiation · HR: APBI vs WBI

LIMITATIONS

Power and follow-up

1. **Underpowered: 28 of 208 planned events; 5-year recurrence with WBI was 0.8% against an assumed 4%.**

2. **Analyses are censored at 5 years in a mostly hormone receptor-positive population; late recurrences are not captured.**

3. **Adverse events and cosmetic outcome are not reported here (published in 2023). Modified intention to treat: 84 randomised patients excluded (34 vs 50). Open-label.**

WBI: whole-breast irradiation

INTERPRETATION

> At 5 years, ipsilateral breast tumour recurrence was 0.8% with whole-breast irradiation and 1.0% with external-beam accelerated partial-breast irradiation; the prespecified noninferiority criterion was not met.

REFERENCE

Meduri B, Baldissera A, Iotti C, et al. Partial-Breast Irradiation Versus Whole-Breast Irradiation for Low-Risk Invasive Breast Carcinoma: 5-Year Results of the Multicenter, Randomized, Phase III IRMA Trial. J Clin Oncol 2026; published online November 17. doi:10.1200/JCO-26-00969. ClinicalTrials.gov NCT01803958.

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Educational content for healthcare professionals. Not medical advice. Produced with AI assistance; figures checked against the full text.

10-year follow-up is ongoing.

RadiotherapyWatch