AVANT GUARD IDE clinical trial

Wazni, OM et al., 2026. Pulsed Field Ablation as Initial Therapy for Persistent Atrial Fibrillation. N Engl J Med. doi:10.1056/NEJMoa2600929

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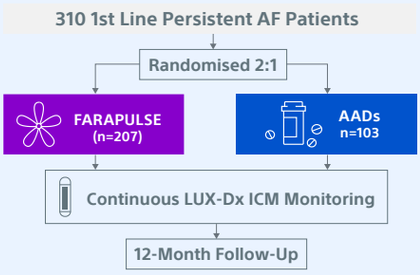
STUDY OBJECTIVE

AVANT GUARD is a randomised controlled IDE trial comparing FARAPULSE™ PFA (with the FARAWAVE™ Pulsed Field Ablation (PFA) Catheter) to antiarrhythmic drug (AAD) therapy to assess the safety and effectiveness of first-line treatment for patients with persistent atrial fibrillation (persAF).

STUDY DESIGN

- 310 first-line persAF patients were randomised 2:1, PFA: AAD in 58 global centres
- Continuous rhythm monitoring was performed with the LUX-Dx™ Insertable Cardiac Monitoring (ICM) System in all patients
- 207 patients underwent pulmonary vein isolation (PVI) and posterior wall ablation (PWA) using the FARAWAVE catheter



RESULTS

EFFICACY

FARAWAVE PFA Catheter demonstrated superiority* over AADs
with significantly higher primary effectiveness.

**One-sided log-rank p-value <0.001*

Primary Endpoints Met

Primary effectiveness at 12 months

56.0% FARAWAVE catheter** vs **30.1%** AADs

***Hazard Ratio: 0.46 | 95% CI, 0.33 to 0.65*

Novel effectiveness endpoint: more comprehensive recurrence analysis
Consistent with prior pivotal AF trials, a component of the primary effectiveness endpoint measures symptomatic episodes of ≥30 seconds. AVANT GUARD goes further by using continuous rhythm monitoring via the LUX-Dx ICM to capture ≥1-hour asymptomatic episodes. This novel endpoint provides a more comprehensive assessment of the true clinical burden of AF.

Significantly more patients had no recurrence†
when treated with the FARAWAVE PFA Catheter

†CI (7.3%, 31.6%) | p-value <0.001††

Zero recurrence at 12 months

51.7% FARAWAVE catheter vs **32.2%** AADs

SAFETY

The major adverse event rate§ was significantly lower than the pre-defined safety performance goal.

CONCLUSIONS

AVANT GUARD met its primary endpoints and **demonstrated superior efficacy over AAD therapy,** adding to the extensive and rigorous clinical evidence supporting FARAPULSE PFA.

Endpoint definitions. Composite Primary Effectiveness Endpoints

PFA: Acute procedural success defined as acute isolation of all PVs assessed ≥20 min after last PV lesion and acute isolation of LAPW and chronic ablation success through 12 months defined as freedom from the use of amiodarone between randomisation through 12 months and freedom from the following after the 3-month blanking period: (1)symptomatic AF, AFL, or AT recurrence ≥ 30s, (2) asymptomatic recurrence of AF, AFL, or AT ≥ 1 hour, (3) any electrical cardioversion or reablation for AF, AFL, or AT, and (4) any use of Class I or III AAD.

AADs: Acute success is defined as no ablation performed during the blanking period. Chronic success is defined as freedom from the use of amiodarone between randomisation through 12 months and freedom from any of the following after the 3-month blanking period: (1) symptomatic AF, AFL, or AT recurrence ≥ 30s, (2) asymptomatic recurrence of AF,AFL, or AT ≥ 1 hour, and (3) any electrical cardioversion or ablation for AF, AFL, or AT.

Composite Primary Safety Endpoint: A composite endpoint defined as: 1) serious adverse event related to either the use of an ablation catheter or the ablation procedure with onset within 7 days of the primary procedure, 2) death, cardiac tamponade/perforation, pericarditis, cardiovascular or pulmonary adverse event related to either the use of the ablation system or procedure out to 30 days and 3) pulmonary vein stenosis or atrio-oesophageal fistula out to 12 months.

†† Exploratory endpoint comparing distribution of post-blanking AA burden in patients randomised to PFA vs AADs.

§ The major device or procedure related adverse event rate was 5.1% [8.6% one-sided 97.5% UCL] at 12-months which was significantly lower than the pre-defined safety performance goal of 12%.

Wazni OM, Chun JKR, Nair DG, et al. (2026) Pulsed Field Ablation as Initial Therapy for Persistent Atrial Fibrillation. *N Engl J Med*. Published online April 25, 2026. doi:10.1056/NEJMoa2600929

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