TREATMENTS FOR PIK3CA-MUTATED IN ADVANCE OR METASTATIC BREAST CANCER: A SYSTEMATIC REVIEW

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Background and importance

Alterations in components of the PI3K pathway are frequently observed in estrogen receptor (ER) positive. Mutations in PIK3CA (PIK3CA+), which encodes the alpha isoform of the catalytic subunit of PI3K, are detected in over 40% percent of ER+ breast cancers (BC).

Aim and objectives

To develop a systematic review of therapies for advanced and metastatic BC with PIK3CA-mutated (PIK3CA+).

Material and methods

PRISMA methodology

A literature search in PubMed® database was performed until September 2025.

- Inclusion criteria: randomized clinical trials (RCTs) enrolling patients diagnosed with ER+, HER2- and PIK3CA+ advanced and/or metastatic BC.
- Efficacy endpoints: overall survival (OS), progression-free survival (PFS) and objective response rate (ORR).
- Data collected: publication date, study design, tumor stage, sample size, population follow-up, treatments and efficacy results.

Results

73 search results → 11 RCTs met the inclusion criteria.

- All studies were placebo-controled.
- Median follow-up: 8 - 54 months.
- Sample size: 28 - 516 patients.
- Therapies: alpelisib plus fulvestrant, buparlisib with paclitaxel, buparlisib plus fulvestrant, capivasertib with paclitaxel, capivasertib plus fulvestrant, ipatasertib with paclitaxel, pictilisib plus fulvestrant and taselisib with fulvestrant.

Alpelisib plus fulvestrant and capivasertib plus fulvestrant achieved the highest numerical efficacy.

Buparlisib plus fulvestrant presented the next best numerical efficacy.

Therapy	OS	PFS	ORR
Alpelisib plus fulvestrant	39.3 months (24.4-44.9)	11.0 months (7.5-14.5)	Not available
Capivasertib plus fulvestrant	38.9 months (23.3-50.7)	12.8 months (6.6-18.8)	Not available
Buparlisib plus fulvestrant	33.6 months (23.8-40.0)	7.0 months (5.0-10.0)	18.4% (10.9-28.1)

Conclusion and relevance

- Eight regimens with combinations of drugs for the treatment of advanced or metastatic BC with PIK3CA+ were found.
- Capivasertib plus fulvestrant and alpelisib plus fulvestrant. suggested a similar efficacy result.

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