



Allegheny Health Network

Nivolumab/Ipilimumab Compared to Capecitabine for Triple Negative Breast Cancer Patients with Residual Disease After Neoadjuvant Chemotherapy – Final Results of BreastImmune-03, A Multicenter Randomized Open-label Phase II Trial

BACKGROUND

Residual Cancer Burden (RCB) after neoadjuvant chemo is associated with prognosis.

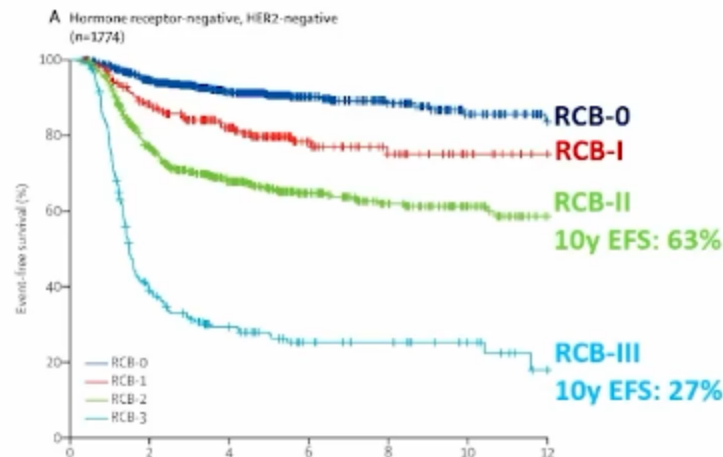
Event Free Survival (EFS) is poor for pts with RCB-II or RCB-III disease¹.

Before the pembrolizumab era, capecitabine was a treatment option in the postoperative/adjuvant setting for non-pCR TNBC pts².

Yau C, et al. Lancet Oncol 2022;23:149-60

van Mackelenbergh MT, et al. Eur J Cancer 2022;166:185-201

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Number at risk
(number censored)

RCB-0	770 (0)	632 (101)	381 (336)	197 (515)	125 (582)	74 (630)	42 (561)
RCB-1	212 (0)	173 (15)	114 (63)	56 (117)	38 (133)	24 (147)	16 (155)
RCB-2	590 (0)	397 (65)	239 (179)	142 (267)	94 (311)	59 (344)	27 (374)
RCB-3	202 (0)	72 (10)	42 (24)	23 (37)	18 (42)	11 (49)	3 (55)



BREASTIMMUNE-03

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POPULATION

Patients with early TNBC
Previously treated with
neoadjuvant chemotherapy
followed by breast/node surgery
Who did not receive any immune
checkpoint inhibitor
RCB-II or RCB-III
PS ECOG 0-1

R*

N**= 114

NIVOLUMAB

360mg IV q3w, 8 cycles

+

IPIILIMUMAB

1mg/kg IV q6w, 4 cycles

CAPECITABINE

1000mg/m² BID
d1-d14, q3w, 8 cycles

ENDPOINTS

Primary endpoint

- Invasive Disease Free Survival (iDFS)

Secondary endpoints

- Overall Survival,
Local/regional Recurrence (LR) rate,
Distant Recurrence-(DR) free survival
- Safety according to CTCAE 5.0
- HR-QoL (QLQ C30, BR-23, FA-12)
- Translational research

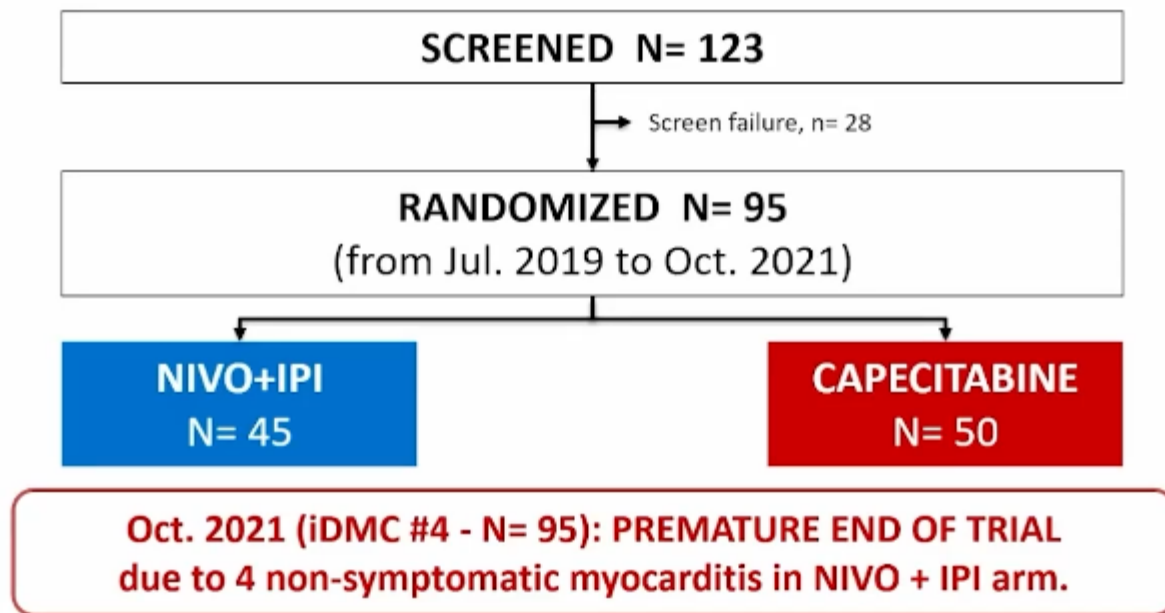
*: Stratification factors: PS ECOG, centers and RCB score

** : 114 pts to detect an improvement of the 2-year iDFS rate from 60 to 80% (HR: 0.54; 80% power, α :5%)



CONSORT

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PATIENTS

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Characteristics

N (%) or as specified

Age, median [min-max]

NIVO+IPI

N= 45

CAPECITABINE

N= 50

Histology

NST

44 (98)

48 (96)

Other

1 (2)

2 (4)

Initial tumor classification

T1 - T2

33 (73)

39 (78)

T3 - T4

12 (27)

10* (20)

Node involvement

Positive

23 (51)

22^S (44)

Negative

22 (49)

24 (48)

Grade

Grade II

13 (29)

15 (30)

Grade III

32 (71)

35 (70)

Residual Cancer Burden

RCB-II

27 (60)

30 (60)

RCB-III

18 (40)

20 (40)

Play

*Tx for 1 pt; ^SNx for 4 pts

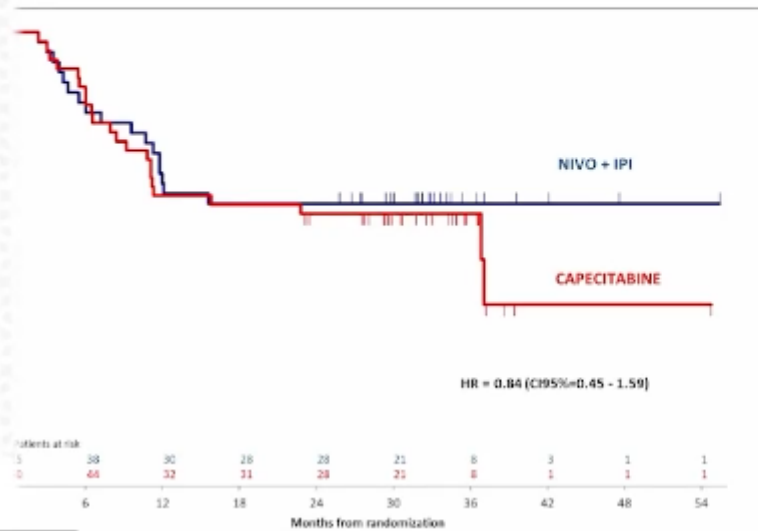


RESULTS

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With a median follow-up of 34.3 months: no significant difference for iDFS



Endpoints	NIVO+IPI N= 45	CAPECITABINE N= 50
95% IC		
Nb relapse (%)	17 (38)	22 (44)
iDFS - 3y	62%	60%
	0.46 – 0.75	0.45 – 0.72
OS - 3y	75%	73%
	0.59 – 0.85	0.58 – 0.84
LR free survival - 3y	85%	88%
	0.69 – 0.93	0.74 – 0.95
DR free survival - 3y	71%	68%
	0.55 – 0.82	0.53 – 0.79

SAFETY

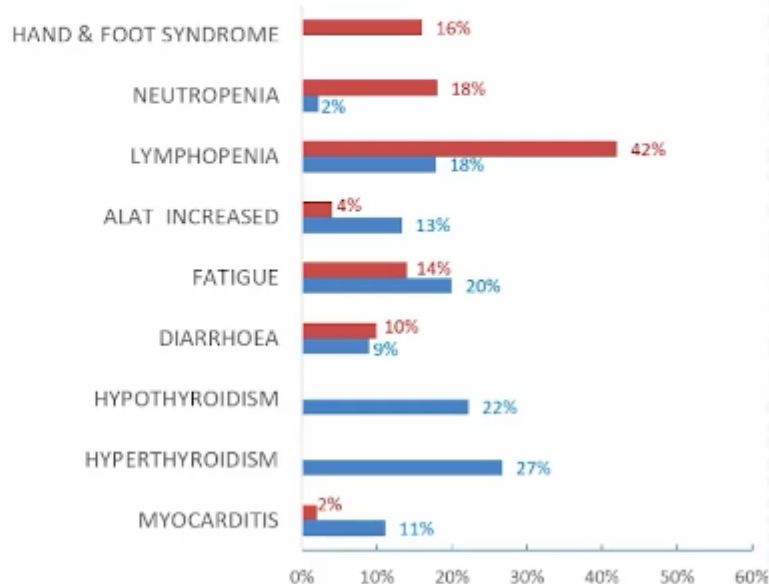
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Overview

Number of pts with ≥ 1 AE (%)	NIVO+IPI N=45	CAPECITABINE N=50
Related AE	43 (96)	48 (96)
Related Gr. ≥ 2 AE	39 (87)	32 (64)
Related Gr. ≥ 3 AE	22 (49)	22 (44)
Leading to treat. discontinuation	17 (38)	7 (14)
Related SAE	11 (24)	3 (6)

■ Most common ($\geq 10\%$) related AE Gr. ≥ 2



CONCLUSIONS

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- There is no statistically difference in the clinical outcome for NIVO+IPI **vs** capecitabine in the postoperative setting after neoadjuvant chemotherapy for RCB-II or RCB-III pts.
- Immune-mediated AE may limit the use of the NIVO+IPI combination in this setting.
- The recent standard use of neoadjuvant pembrolizumab for stage II/III eTNBC further limits the interpretation of BreatImmune-03 data.
- Translational studies are ongoing on initial tumor biopsies (from diagnosis), surgical specimen and relapse/metastatic tumor samples:
 - genomic and transcriptomic (WES & RNAseq)
 - immune infiltration (Multiplex IF).

