Table SI. Characteristics of the randomized controlled trials included in the present meta-analysis comparing the efficacy and safety of ICI-based immunotherapy combined with chemotherapy and other treatments for unresectable locally advanced or metastatic TNBC.

First author/s, year	Trial name	Country	TRN	Blinding	Median age (range), years		Treatment programmes (patient number)		Trial phase	Total patients, n	Primary outcomes	Secondary outcomes	Range of dates of the trial	(Refs.)
					Experimental group	Control group	Experimental group	Control group						
Schmid, 2018	IMpassion130	UK	NCT02425891	Double-blind (participant, investigator)	59 (20-82)	56 (26-86)	Atezolizumab + nab-paclitaxel (451)	Placebo + nab-paclitaxel s(451)	III	902	PFS, OS	OR, CR, PR, DOR, TTD, AEs	June 2015-August 2021	(29)
Brufsky, 2021	COLET	USA	NCT02322814	None (open-label)	52 (26-77)	55 (34-73)	Cobimetinib + atezolizumab + paclitaxel (32)	Cobimetinib + paclitaxel (47)	II	79	PFS, OR, PR, CR	OS, DOR, EOT, AEs	March 2015-September 2021	(35)
Cortes, 2022	KEYNOTE-355	Spain	NCT02819518	Quadruple-blind (participant, care, provider, investigator)	53 (44-63）	53 (43-63)	Pembrolizumab + chemotherapy (nab-paclitaxel, paclitaxel, or gemcitabine plus carboplatin) (566)	Placebo + chemotherapy (281)	III	847	PFS	OR, DOR, DCR	July 2016-November 2023	(32)
Bachelot, 2021	SAFIR02-BREAST IMMUNO	France	NCT02299999	None (open-label)	56 (27-79)	56.5 (24-77)	Durvalumab (47)	Maintenance chemotherapy (35)	II	82	PFS	OS, ORR, AEs	April 2014-December 2023	(31)
Hattori, 2023	KEYNOTE-355	Japan	NCT02819518	Quadruple-blind (participant, care, provider, investigator)	54 (29-76)	51 (25-74)	Pembrolizumab + chemotherapy (61)	Placebo + chemotherapy (26)	III	87	PFS, OS	AEs, ORR, DOR, DCR	July 2016-November 2023	(33)
Miles, 2021	IMpassion131	UK	NCT03125902	Double-blind (participant, investigator)	54 (22-85)	53 (25-81)	Atezolizumab + paclitaxel (431)	Placebo + paclitaxel (220)	III	651	PFS	OS, ORR, AEs	August 2017-January 2023	(36)
Røssevold, 2022	ALICE	USA	NCT03164993	Double-blind (participant, investigator)	52.5 (28-74)	58.5 (31-77)	Atezolizumab and chemotherapy (40)	Placebo and chemotherapy (28)	IIb	68	PFS	ORR, DOR, DRR, CBR, OS	May 2017-December 2028	(30)
Winer, 2021	KEYNOTE-119	USA	NCT02555657	None (open-label)	50 (43-59)	53 (44-61)	Pembrolizumab (312)	Chemotherapy (capecitabine, eribulin, gemcitabine or vinorelbine) (310)	III	622	OS	PFS, ORR, DOR, DCR, AEs	September 2015-May 2020	(34)

TRN, trial registration number; PFS, progression-free survival; OS, overall survival; OR, odds ratio; RR, relative risk; AEs, adverse events; ORR, objective response rate; PR, partial response; CR, complete response; DCR, disease control rate; DOR, duration of response; CBR, clinical benefit rate; nab, albumin-bound nanoparticles.

Table SII. Subgroup analysis of any grade of AEs induced by immunotherapy with immune checkpoint inhibitors alone or in combination with other treatments versus other treatment modalities in locally advanced or metastatic triple-negative breast cancer.

AE	Studies, n	Experimental group (patients, n)	Control group (patients, n)	RR	95% CI	P-value	Heterogeneity (I^2, %)
Alopecia	6	1,849	1,300	0.89	(0.70, 1.14)	0.36	79
Anaemia	6	11,849	1,300	0.96	(0.75, 1.22)	0.72	76
Cough	4	1,226	993	1.29	(1.06, 1.57)	0.01	0
Diarrhoea	4	1,226	993	0.83	(0.59, 1.19)	0.31	83
Decreased appetite	5	1,287	1,019	0.64	(0.29, 1.39)	0.26	86
Fatigue	6	1,828	1,302	1.02	(0.92, 1.13)	0.74	0
Hypothyroidism	3	1,194	946	4.52	(2.95, 6.94)	<0.00001	40
Nausea	7	1,889	1,328	0.93	(0.76, 1.14)	0.49	71
Neutropenia	7	1,961	1,347	0.97	(0.68, 1.38)	0.86	84
Pyrexia	4	1,226	993	1.42	(1.15, 1.83)	0.002	49
Rash	4	957	729	1.10	(0.90, 1.33)	0.36	8
Pruritus	4	1,226	993	0.80	(0.26, 2.48)	0.70	93
Asthenia	4	1,226	993	1.00	(0.81, 1.23)	0.99	0

AEs, adverse events; RR, risk ratio; CI, confidence interval.