Clinical trials of immune checkpoint inhibition for melanoma in all type of patients

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1 anti-CTLA-4

Trial	Treatments	Patients	Trials design and methods
ipilimumab + dacarbazine vs dacarbazine			
Robert , 2011 [NCT00324155] n=NA follow-up:	ipilimumab (10 mg per kilogram) plus dacarbazine (850 mg per square meter of body-surface area) versus dacarbazine (850 mg per square meter)	patients with previously untreated metastatic melanoma (stage III (unresectable) orstage IV)	Parallel groups double blind
ipi + gp100 vs gp100			
Hodi (ipi + gp100) , 2010 [NCT00094653] n=403/136 follow-up:	Ipilimumab, at a dose of 3 mg per kilogram of body weight, was administered with gp100 every 3 weeks for up to four treatments versus gp100 alone	patients with previously treated metastatic melanoma patients with unresectable stage III or IV melanoma, whose disease had progressed while they were receiving therapy for metastatic disease	Parallel groups open-label
ipilimumab 3 mg/kg vs gp100			
Hodi (ipi alone) , 2010 [NCT00094653] n=137/136 follow-up:	ipilimumab 3mg/kg every 3 weeks up to 4 treatments versus gp100 alone	patients with previously treated metastatic melanoma patients with unresectable stage III or IV melanoma, whose disease had progressed while they were receiving therapy for metastatic disease	Parallel groups open-label
ipilimumab vs placebo			
EORTC 18071 (Eggermont) , 2015 [NCT00636168] n=475/476 follow-up: 5.3 years	ipilimumab at a dose of 10 mg per kilogram every 3 weeks for four doses, then every 3 months for up to 3 years or until disease recurrence or an unacceptable level of toxic effects occurred versus placebo	high risk patients who had undergone complete resection of stage III melanoma	Parallel groups double-blind

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Hodi (ipi alone), 2010:

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2 anti-PD-1

Trial	Treatments	Patients	Trials design and methods
nivolumab vs chemotherapy			
CheckMate 037 (Weber) , 2015 [NCT01721746] n=272/133 follow-up:	ntravenous infusion of nivolumab 3 mg/kg every 2 weeks until progression or unacceptable toxic eff ects versus investigators choice of chemotherapy (dacarbazine 1000 mg/m every 3 weeks or paclitaxel 175 mg/m combined with carboplatin area under the curve 6 every 3 weeks)	patients with advanced melanoma who progressed after ipilimumab, or ipilimumab and a BRAF inhibitor if they were BRAFV mutation-positive (second-line or later-line treatment)	Parallel groups open-label
pembrolizumab 10mg/kg vs chemotherapy			
KEYNOTE 002 (10mg/kg Q3W) , 2015 [NCT01704287] n=181/179 follow-up:	intravenous pembrolizumab 10 mg/kg every 3 weeks versus investigator-choice chemotherapy (paclitaxel plus carboplatin, paclitaxel, carboplatin, dacarbazine, or oral temozolomide)	patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAFV600 mutation positive, a BRAF inhibitor	Parallel groups open design
pembrolizumab 2mg/kg vs chemotherapy			
KEYNOTE 002 (2mg/kg Q3W) , 2015 [NCT01704287] n=180/179 follow-up:	Pembrolizumab 2 mg/kg IV Q3W versus investigator-choice chemotherapy (paclitaxel plus carboplatin, paclitaxel, carboplatin, dacarbazine, or oral temozolomide)	patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAFV600 mutation positive, a BRAF inhibitor	Parallel groups open design
nivolumab vs dacarbazine			

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Trial	Treatments	Patients	Trials design and methods
CheckMate 066 (Robert) , 2015 [NCT01721772] n=210/208 follow-up:	nivolumab at a dose of 3 mg per kilogram of body weight every 2 weeks versus dacarbazine at a dose of 1000 mg per square meter of body-surface area every 3 weeks	previously untreated patients who had unresectable metastatic melanoma without a BRAF mutation (stage III or IV)	Parallel groups double-blind
nivolumab vs ipilimumab			
CheckMate 067 (nivo vs ipi) , 2015 [NCT01844505] n=316/315 follow-up:	3 mg of nivolumab per kilogram of body weight every 2 weeks versus 3 mg of ipilimumab per kilogram every 3 weeks for 4 doses	Previously Untreated Advanced Melanoma	Parallel groups double-blind
CheckMate 238 , 2017 [NCT02388906] n=453/453 follow-up: 18 months (median)	nivolumab at a dose of 3 mg per kilogram of body weight every 2 weeks versus ipilimumab at a dose of 10 mg per kilogram every 3 weeks for four doses and then every 12 weeks	patients with Complete Resection of Stage IIIb/c or Stage IV Melanoma	Parallel groups double-blind US
nivolumab + ipilimumab vs ipilimumab			
CheckMate 067 (nivo + ipi vs ipi) , 2015 [NCT01844505] n=314/315 follow-up:	1mg of nivolumab per kilogram every 3 weeks plus 3 mg of ipilimumab per kilogram every 3 weeks for 4 doses, followed by 3 mg of nivolumab per kilogram every 2 weeks for cycle 3 and beyond versus 3 mg of ipilimumab per kilogram every 3 weeks for 4 doses	Previously Untreated Advanced Melanoma	Parallel groups double-blind
Postow , 2015 [NCT01927419] n=NA follow-up:	-	patients with metastatic melanoma who had not previously received treatment,	Parallel groups double-blind
pembrolizumab (every 2W) vs ipilimumab			
KEYNOTE-006 (every 2W) , 2015 [NCT01866319] n=NA follow-up:	pembrolizumab (at a dose of 10 mg per kilogram of body weight) every 2 weeks or every 3 weeks versus four doses of ipilimumab (at 3 mg per kilogram) every 3 weeks	patients with advanced melanoma who had received no more than one previous systemic therapy for advanced disease	Parallel groups open-label
pembrolizumab (every 3W) vs ipilimumab			
KEYNOTE-006 (every 3W) , 2015 [NCT01866319] n=277/278 follow-up:	Pembrolizumab Every 3 Weeks versus Ipilimumab (Participants receive ipilimumab, 3 mg/kg IV, once every 3 weeks for a total oPembrolizumab Every 2 Weeks (Participants receive pembrolizumab, 10 mg intravenously (IV), once every 2 weeks for up to 2 years) 2/ Pembrolizumab Every 3 Weeks (P	patients with unresectable stage III or IV advanced melanoma and who had received no more than one previous systemic therapy for advanced disease	Parallel groups open label

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Trial	Treatments	Patients	Trials design and methods
nivolumab + ipilimumab vs nivolumab			
CheckMate 067 (nivo + ipi vs nivo) , 2015 [NCT01844505] n=314/316 follow-up:	Nivolumab + ipilumab versus nivolumab alone	Previously Untreated Advanced Melanoma	Parallel groups double-blind
pembrolizumab 2mg/kg vs pembrolizumab 10mg/kg			
KEYNOTE-001 , 2014 [NCT01295827] n=89/84 follow-up:	intravenous pembrolizumab at 2 mg/kg every 3 weeks versus intravenous pembrolizumab at 10 mg/kg every 3 weeks	patients (aged 18 years) with advanced melanoma whose disease had progressed after at least two ipilimumab doses	Parallel groups open-label
pembrolizumab vs placebo			
KEYNOTE-054 , 2018 [NCT02362594] n=514/505 follow-up: 15 months (median)	Pembrolizumab (Participants receive pembrolizumab 200 mg intravenously (IV) on Day 1 of each 21-day cycle for up to 1 year) versus placebo	patients with complete Resection of High-Risk Stage III Melanoma	Parallel groups double-blind

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3 About TrialResults-center.org

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