Clinical trials of immune checkpoint inhibition for melanoma in adjuvant setting

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1 anti-CTLA-4

Trial	Treatments	Patients	Trials design and methods
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

References

EORTC 18071 (Eggermont), 2015:

Eggermont AM, Chiarion-Sileni V, Grob JJ, Dummer R, Wolchok JD, Schmidt H, Hamid O, Robert C, Ascierto PA, Richards JM, Lebb C, Ferraresi V, Smylie M, Weber JS, Maio M, Konto C, Hoos A, de Pril V, Gurunath RK, de Schaetzen G, Suciu S, Testori A Adjuvant ipilimumab versus placebo after complete resection of high-risk stage III melanoma (EORTC 18071): a randomised, double-blind, phase 3 trial. Lancet Oncol 2015;16:522-30 [25840693]

Eggermont AM, Chiarion-Sileni V, Grob JJ, Dummer R, Wolchok JD, Schmidt H, Hamid O, Robert C, Ascierto PA, Richards JM, Lebb C, Ferraresi V, Smylie M, Weber JS, Maio M, Bastholt L, Mortier L, Thomas L, Tahir S, Hauschild A, Hassel JC, Hodi FS, Taitt C, d Prolonged Survival in Stage III Melanoma with Ipilimumab Adjuvant Therapy. N Engl J Med 2016;375:1845-1855 [27717298]

2 anti-PD-1

Trial	Treatments	Patients	Trials design and methods
nivolumab vs ipilimumab			
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
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

References

CheckMate 238, 2017:

Weber J, Mandala M, Del Vecchio M, Gogas HJ, Arance AM, Cowey CL, Dalle S, Schenker M, Chiarion-Sileni V, Marquez-Rodas I, Grob JJ, Butler MO, Middleton MR, Maio M, Atkinson V, Queirolo P, Gonzalez R, Kudchadkar RR, Smylie M, Meyer N, Mortier L, Atkins MB Adjuvant Nivolumab versus Ipilimumab in Resected Stage III or IV Melanoma. N Engl J Med 2017;: [28891423]

KEYNOTE-054, 2018:

Eggermont AMM, Blank CU, Mandala M, Long GV, Atkinson V, Dalle S, Haydon A, Lichinitser M, Khattak A, Carlino MS, Sandhu S, Larkin J, Puig S, Ascierto PA, Rutkowski P, Schadendorf D, Koornstra R, Hernandez-Aya L, Maio M, van den Eertwegh AJM, Grob JJ, Gut Adjuvant Pembrolizumab versus Placebo in Resected Stage III Melanoma. N Engl J Med 2018;: [29658430]

3 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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