

ENERO

Randomized, Double-Blind, Phase III Trial of Ipilimumab Versus Placebo in Asymptomatic or Minimally Symptomatic Patients With Metastatic Chemotherapy-Naive Castration-Resistant Prostate Cancer.

Beer, Tomasz M., Kwon, Eugene D., Drake, Charles G., Fizazi, Karim, Logothetis, Christopher, Gravis, Gwenaëlle, Ganju, Vinod, Polikoff, Jonathan, Saad, Fred, Humanski, Piotr, Piulats, Josep M., Gonzalez Mella, Pablo, Ng, Siobhan S., Jaeger, Dirk, Parnis, Francis X., Franke, Fabio A., **PUENTE VÁZQUEZ, JAVIER**, Carvajal, Roman, Sengelov, Lisa, McHenry, M. Brent, Varma, Arvind, van den Eertwegh, Alfonsus J., Gerritsen, Winald

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Randomized, double-blind, phase III trial of ipilimumab versus placebo in asymptomatic or minimally symptomatic patients with metastatic chemotherapy-naive castration-resistant prostate cancer

Tomasz M. Beer, Eugene D. Kwon, Charles G. Drake, Karim Fizazi, Christopher Logothetis, Gwenaëlle Gravis, Vinod Ganju, Jonathan Polikoff, Fred Saad, Piotr Humanski, Josep M. Piulats, Pablo Gonzalez Mella, Siobhan S. Ng, Dirk Jaeger, Francis X. Parnis, Fabio A. Franke, Javier Puente, Roman Carvajal, Lisa Sengelov, M. Brent McHenry & 3 others

Research output: Contribution to journal › Article

Abstract

Purpose: Ipilimumab increases antitumor T-cell responses by binding to cytotoxic T-lymphocyte antigen 4. We evaluated treatment with ipilimumab in asymptomatic or minimally symptomatic patients with chemotherapy-naive metastatic castration-resistant prostate cancer without visceral metastases. **Patients and Methods:** In this multicenter, double-blind, phase III trial, patients were randomly assigned (2:1) to ipilimumab 10 mg/kg or placebo every 3 weeks for up to four doses. Ipilimumab 10 mg/kg or placebo maintenance therapy was administered to nonprogressing patients every 3 months. The primary end point was overall survival (OS). **Results:** Four hundred patients were randomly assigned to ipilimumab and 202 to placebo: 399 were treated with ipilimumab and 199 with placebo. Median OS was 28.7 months (95% CI, 24.5 to 32.5 months)

FEBRERO

Oxidized LDL Is Associated With Metabolic Syndrome Traits Independently of Central Obesity and Insulin Resistance

Hurtado-Roca, Yamilee, Bueno, Hector, **FERNÁNDEZ ORTIZ, ANTONIO IGNACIO**, Ordovas, Jose Maria, IBÁÑEZ CABEZA, BORJA, Fuster, Valentin, Rodriguez-Artalejo, Fernando, Laclaustra, Martin

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Oxidized LDL Is Associated With Metabolic Syndrome Traits Independently of Central Obesity and Insulin Resistance

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Abstract

This study assesses whether oxidative stress, using oxidized LDL (ox-LDL) as a proxy, is associated with metabolic syndrome (MS), whether ox-LDL mediates the association between central obesity and MS, and whether insulin resistance mediates the association between ox-LDL and MS. We examined baseline data from 3,987 subjects without diabetes from the Insulin Resistance Atherosclerosis (IRAS) Study. For the second third

MARZO

Cardiopietic cell therapy for advanced ischaemic heart failure: results at 39 weeks of the prospective, randomized, double blind, sham-controlled CHART-1 clinical trial

Bartunek, Jozef, Terzic, Andre, Davison, Beth A., Filippatos, Gerasimos S., Radovanovic, Slavica, Beleslin, Branko, Merkely, Bela, Musialek, Piotr, Wojakowski, Wojciech, Andreka, Peter, Horvath, Ivan G., Katz, Amos, Dolatabadi, Dariouch, El Nakadi, Badih, Arandjelovic, Aleksandra, Edes, Istvan, Seferovic, Petar M., Obradovic, Slobodan, Vanderheyden, Marc, Jagic, Nikola, Petrov, Ivo, Atar, Shaul, Halabi, Majdi, Gelev, Valeri L., Shochat, Michael K., Kasprzak, Jaroslaw D., Sanz-Ruiz, Ricardo, Heyndrickx, Guy R., Nyolczas, Noemi, Legrand, Victor, Guedes, Antoine, Heyse, Alex, Moccetti, Tiziano, Fernandez-Aviles, Francisco, **JIMÉNEZ QUEVEDO, PILAR**, Bayes-Genis, Antoni, Maria Hernandez-Garcia, Jose, Ribichini, Flavio, Gruchala, Marcin, Waldman, Scott A., Teerlink, John R., Gersh, Bernard J., Povsic, Thomas J., Henry, Timothy D., Metra, Marco, Hajjar, Roger J., Tendra, Michal, Behfar, Atta, Alexandre, Bertrand, Seron, Aymeric, Stough, Wendy Gattis, Sherman, Warren, Cotter, Gad, Wijns, William, CHART Program

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Cardiopietic cell therapy for advanced ischaemic heart failure: results at 39 weeks of the prospective, randomized, double blind, sham-controlled CHART-1 clinical trial

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See "The quest for a successful cell-based therapeutic approach for heart failure" with doi: 10.1093/eurheartj/ehw626. This article has been cited by other articles in PMC.

Abstract

Aims

Cardiopietic cells, produced through cardiogenic conditioning of patients' mesenchymal stem cells, have shown preliminary efficacy. The Congestive Heart Failure Cardiopietic Regenerative Therapy (CHART-1) trial aimed to

ABRIL

Direct Comparison of 4 Very Early Rule-Out Strategies for Acute Myocardial Infarction Using High-Sensitivity Cardiac Troponin I

Boeddinghaus, Jasper, Nestelberger, Thomas, Twerenbold, Raphael, Wildi, Karin, Badertscher, Patrick, Cupa, Janosch, Burge, Tobias, Machler, Patrick, Corbiere, Sydney, Grimm, Karin, Gimenez, Maria Rubini, Puelacher, Christian, Shrestha, Samyut, Widmer, Dayana Flores, Fuhrmann, Jakob, Hillinger, Petra, Sabti, Zaid, Honegger, Ursina, Schaerli, Nicolas, Kozhuharov, Nikola, Rentsch, Katharina, Miro, Oscar, Lopez, Beatriz, **MARTÍN SÁNCHEZ, FRANCISCO JAVIER, RODRIGUEZ ADRADA, ESTHER**, Morawiec, Beata, Kaweck, Damian, Ganovska, Eva, Parenica, Jiri, Lohrmann, Jens, Kloos, Wanda, Buser, Andreas, Geigy, Nicolas, Keller, Dagmar I., Osswald, Stefan, Reichlin, Tobias, Mueller, Christian

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Direct Comparison of 4 Very Early Rule-Out Strategies for Acute Myocardial Infarction Using High-Sensitivity Cardiac Troponin I.

Boeddinghaus J¹, Nestelberger T¹, Twerenbold R¹, Wildi K¹, Badertscher P¹, Cupa J¹, Burge T¹, Machler P¹, Corbiere S¹, Grimm K¹, Gimenez MB¹, Puelacher C¹, Shrestha S¹, Flores Widmer D¹, Fuhrmann J¹, Hillinger P¹, Sabti Z¹, Honegger U¹, Schaerli N¹, Kozhuharov N¹, Rentsch K¹, Miro O¹, Lopez B¹, Martín-Sánchez FJ¹, Rodríguez-Adrada E¹, Morawiec B¹, Kaweck D¹, Ganovská E¹, Parenica J¹, Lohrmann J¹, Kloos W¹, Buser A¹, Geigy N¹, Keller C¹, Osswald S¹, Reichlin T¹, Mueller C².

Author information

Abstract

BACKGROUND: Four strategies for very early rule-out of acute myocardial infarction using high-sensitivity cardiac troponin I (hs-cTnI) have been identified. It remains unclear which strategy is most attractive for clinical application.

METHODS: We prospectively enrolled unselected patients presenting to the emergency department with symptoms suggestive of acute myocardial infarction. The final diagnosis was adjudicated by 2 independent cardiologists. Hs-cTnI levels were measured at presentation and after 1 hour in a blinded fashion. We directly compared all 4 hs-cTnI-based rule-out strategies: limit of detection (LOD, hs-cTnI < 2 ng/L), single cutoff (hs-cTnI < 5 ng/L), 1-hour algorithm (hs-cTnI < 5 ng/L and 1-hour change < 2 ng/L), and the 0/1-hour algorithm recommended in the European Society of Cardiology guideline combining LOD and 1-hour algorithm.

RESULTS: Among 2828 enrolled patients, acute myocardial infarction was the final diagnosis in 451 (16%) patients. The LOD approach ruled out 453 patients (16%) with a sensitivity of 100% (95% confidence interval [CI], 99.2%-100%), the single cutoff 1516 patients (54%) with a sensitivity of 97.1% (95% CI, 95.1%-98.3%), the 1-hour algorithm 1459 patients (52%) with a sensitivity of 98.4% (95% CI, 96.8%-99.2%), and the 0/1-hour algorithm 1463 patients (52%) with a sensitivity of 98.4% (95% CI, 96.8%-99.2%). Predefined subgroup analysis in early presenters (≤ 2 hours) revealed significantly lower sensitivity (94.2%, interaction *P* = 0.03) of the single cutoff, but not the other strategies. Two-year survival was 100% with LOD and 98.1% with the other strategies (*P* < 0.01 for LOD versus each of the other strategies).

CONCLUSIONS: All 4 rule-out strategies balance effectiveness and safety equally well. The single cutoff should not be applied in early presenters, whereas the 3 other strategies seem to perform well in this challenging subgroup.

CLINICAL TRIAL REGISTRATION: URL: <http://www.clinicaltrials.gov>. Unique identifier: NCT00470587.

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MAYO

Use of the Instantaneous Wave-free Ratio or Fractional Flow Reserve in PCI

Davies, Justin E, Sen, Sayan, Dehbi, Hakim-Moulay, Al-Lamee, Rasha, Petraco, Ricardo, Nijjer, Sukhjinder S, Bhindi, Ravinay, Lehman, Sam J, Walters, Darren, Sapontis, James, Janssens, Luc, Vrints, Christiaan J, Khashaba, Ahmed, Laine, Mika, Van Belle, Eric, Krackhardt, Florian, Bojara, Waldemar, Going, Olaf, Härle, Tobias, Indolfi, Ciro, Niccoli, Giampaolo, Ribichini, Flavo, Tanaka, Nobuhiro, Yokoi, Hiroyoshi, Takashima, Hiroaki, Kikuta, Yuetsu, Erglis, Andrejs, Vinhas, Hugo, Canas Silva, Pedro, Baptista, Sérgio B, Alghamdi, Ali, Hellig, Farrel, Koo, Bon-Kwon, Nam, Chang-Wook, Shin, Eun-Seok, Doh, Joon-Hyung, Brugaletta, Salvatore, Alegria-Barrero, Eduardo, Meuwissen, Martijin, Piek, Jan J, van Royen, Niels, Sezer, Murat, Di Mario, Carlo, Gerber, Robert T, Malik, Iqbal S, Sharp, Andrew S P, Talwar, Suneel, Tang, Kare, Samady, Habib, Altman, John, Seto, Arnold H, Singh, Jasvinder, Jeremias, Allen, Matsuo, Hitoshi, Kharbanda, Rajesh K, Patel, Manesh R, Serruys, Patrick, **ESCANED BARBOSA, JAVIER**

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ORIGINAL ARTICLE

Use of the Instantaneous Wave-free Ratio or Fractional Flow Reserve in PCI

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Clinical Calculator for Early Mortality in Metastatic Colorectal Cancer: An Analysis of Patients From 28 Clinical Trials in the Aide et Recherche en Cancérologie Digestive Database

Renfro, Lindsay A, Goldberg, Richard M, Grothey, Axel, Sobrero, Alberto, Adams, Richard, Seymour, Matthew T, Heinemann, Volker, Schmolz, Hans-Joachim, Douillard, Jean-Yves, Hurwitz, Herbert, Fuchs, Charles S, **DÍAZ-RUBIO GARCÍA, EDUARDO**, Porschen, Rainer, Tournigand, Christophe, Chibaudel, Benoist, Hoff, Paulo M, Kabbinnar, Fairouz F, Falcone, Alfredo, Tebbutt, Niall C, Punt, Cornelis J A, Hecht, J Randolph, Souglakos, John, Bokemeyer, Carsten, Van Cutsem, Eric, Saltz, Leonard, de Gramont, Aimery, Sargent, Daniel J, ARCAD Clinical Trials Program

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Clinical Calculator for Early Mortality in Metastatic Colorectal Cancer: An Analysis of Patients From 28 Clinical Trials in the Aide et Recherche en Cancérologie Digestive Database.

Renfro LA¹, Goldberg RM¹, Grothey A¹, Sobrero A¹, Adams R¹, Seymour MT¹, Heinemann V¹, Schmolz HJ¹, Douillard JY¹, Hurwitz H¹, Fuchs CS¹, Díaz-Rubio E¹, Porschen R¹, Tournigand C¹, Chibaudel B¹, Hoff PM¹, Kabbinnar FF¹, Falcone A¹, Tebbutt NS¹, Punt CJ¹, Hecht JR¹, Souglakos J¹, Bokemeyer C¹, Van Cutsem E¹, Saltz L¹, de Gramont A¹, Sargent DJ¹, ARCAD Clinical Trials Program.

Author information

Abstract

Purpose Factors contributing to early mortality after initiation of treatment of metastatic colorectal cancer are poorly understood. **Materials and Methods** Data from 22,654 patients enrolled in 28 randomized phase III trials contained in the ARCAD (Aide et Recherche en Cancérologie Digestive) database were pooled. Multivariable logistic regression models for 30-, 60-, and 90-day mortality were constructed, including clinically and statistically significant patient and disease factors and interaction terms. A calculator (nomogram) for 90-day mortality was developed and validated internally using bootstrapping methods and externally using a 10% random holdout sample from each trial. The impact of early progression on the likelihood of survival to 90 days was examined with time-dependent Cox proportional hazards models. **Results** Mortality rates were 1.4% at 30 days, 3.4% at 60 days, and 5.5% at 90 days. Among baseline factors, advanced age, lower body mass index, poorer performance status, increased number of metastatic sites, BRAF mutant status, and several laboratory parameters were associated with increased likelihood of early mortality. A multivariable model for 90-day mortality showed strong internal discrimination (C-index, 0.77) and good calibration across risk groups as well as accurate predictions in the external validation set, both overall and within patient subgroups. **Conclusion** A validated clinical nomogram has been developed to quantify the risk of early death for individual patients during initial treatment of metastatic colorectal cancer. This tool may be used for patient eligibility assessment or risk stratification in future clinical trials and to identify patients requiring more or less aggressive therapy and additional supportive measures during and after treatment.

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