Clinical trials of All mechanism for renal-cell carcinoma (advanced) in first line

TrialResults-center www.trialresultscenter.org

1 bevacizumab

Trial	Treatments	Patients	Trials design and methods
bevacizumab plus interferon alfa vs interferon alpha			
CALGB 90206 , 2010 n=369/363 follow-up:	bevacizumab (10 mg/kg intravenously every 2 weeks) plus IFN- (9 million units subcutaneously three times weekly) versus same dose and schedule of IFN- monotherapy	Patients with previously untreated, metastatic clear cell RCC	Parallel groups
AVOREN , 2007 n=327/322 follow-up:	bevacizumab (10 mg/kg every 2 weeks) plus IFN (9 MIU subcutaneously three times a week) versus IFN plus placebo	patients with previously untreated mRCC	

References

CALGB 90206, 2010:

Rini BI, Halabi S, Rosenberg JE, Stadler WM, Vaena DA, Archer L, Atkins JN, Picus J, Czaykowski P, Dutcher J, Small EJ, Phase III trial of bevacizumab plus interferon alfa versus interferon alfa monotherapy in patients with metastatic renal cell carcinoma: final results of CALGB 90206. J Clin Oncol 2010;28:2137-43. [20368558] 10.1200/JCO.2009.26.5561

Rini BI, Halabi S, Rosenberg JE, Stadler WM, Vaena DA, Ou SS, Archer L, Atkins JN, Picus J, Czaykowski P, Dutcher J, Small EJ, Bevacizumab plus interferon alfa compared with interferon alfa monotherapy in patients with metastatic renal cell carcinoma: CALGB 90206. J Clin Oncol 2008;26:5422-8. [18936475] 10.1200/JCO.2008.16.9847

Rini BI, Halabi S, Taylor J, Small EJ, Schilsky RL, , Cancer and Leukemia Group B 90206: A randomized phase III trial of interferon-alpha or interferon-alpha plus anti-vascular endothelial growth factor antibody (bevacizumab) in metastatic renal cell carcinoma. Clin Cancer Res 2004;10:2584-6. [15102658]

AVOREN, 2007:

Escudier B, Bellmunt J, Ngrier S, Bajetta E, Melichar B, Bracarda S, Ravaud A, Golding S, Jethwa S, Sneller V, Phase III trial of bevacizumab plus interferon alfa-2a in patients with metastatic renal cell carcinoma (AVOREN): final analysis of overall survival. J Clin Oncol 2010;28:2144-50. [20368553] 10.1200/JCO.2009.26.7849

Melichar B, Koralewski P, Ravaud A, Pluzanska A, Bracarda S, Szczylik C, Chevreau C, Filipek M, Delva R, Sevin E, Ngrier S, McKendrick J, Santoro A, Pisa P, Escudier B, First-line bevacizumab combined with reduced dose interferon-alpha2a is active in patients with metastatic renal cell carcinoma. Ann Oncol 2008;19:1470-6. [18408224] 10.1093/annonc/mdn161

Escudier B, Pluzanska A, Koralewski P, Ravaud A, Bracarda S, Szczylik C, Chevreau C, Filipek M, Melichar B, Bajetta E, Gorbunova V, Bay JO, Bodrogi I, Jagiello-Gruszfeld A, Moore N Bevacizumab plus interferon alfa-2a for treatment of metastatic renal cell carcinoma: a randomised, double-blind phase III trial. Lancet 2007;370:2103-11 [18156031]

2 mTor inihibitor

Trial	Treatments	Patients	Trials design and methods
temsirolimus vs interferon alpha			

continued...

Trial	Treatments	Patients	Trials design and methods
ARCC (Hudes) temsirolimus alone , 2007 [NCT00065468] n=209/207 follow-up:	25 mg of intravenoustemsirolimus weekly versus 3 million U of interferon alfa (with an increase to 18 millionU) subcutaneously three times weekly	patients with previously untreated, poor-prognosis metastatic renal-cell carcinoma	
everolimus vs sunitinib			
RECORD 3 , 2014 [NCT00903175] n=238/233 follow-up:	everolimus versus sunitinib	patients with metastatic renal cell carcinoma	Cross over

References

ARCC (Hudes) temsirolimus alone, 2007:

Hudes G, Carducci M, Tomczak P, Dutcher J, Figlin R, Kapoor A, Staroslawska E, Sosman J, McDermott D, Bodrogi I, Kovacevic Z, Lesovoy V, Schmidt-Wolf IG, Barbarash O, Gokmen E, O'Toole T, Lustgarten S, Moore L, Motzer RJ Temsirolimus, interferon alfa, or both for advanced renal-cell carcinoma. N Engl J Med 2007;356:2271-81 [17538086]

RECORD 3, 2014:

Motzer RJ, Barrios CH, Kim TM, Falcon S, Cosgriff T, Harker WG, Srimuninnimit V, Pittman K, Sabbatini R, Rha SY, Flaig TW, Page R, Bavbek S, Beck JT, Patel P, Cheung FY, Yadav S, Schiff EM, Wang X, Niolat J, Sellami D, Anak O, Knox JJ Phase II randomized trial comparing sequential first-line everolimus and second-line sunitinib versus first-line sunitinib and second-line everolimus in patients with metastatic renal cell carcinoma. J Clin Oncol 2014;32:2765-72 [25049330]

3 TKI

Trial	Treatments	Patients	Trials design and methods
apitolisib vs everolimus			
Powles , 2014 n=NA	-	-	
BNC105P + everolimus vs everolimus			
Disruptor-1 n=NA	-	-	
sorafenib vs interferon alpha			
Escudier , 2009 n=97/92 follow-up:	oral sorafenib 400 mg twice daily versus subcutaneous IFN–2a 9 million U three times weekly	patients with untreated, advanced renal cancer.	Parallel groups
sunitinib vs interferon alpha			
Motzer , 2007 [NCT00083889] n=375/375 follow-up:	repeated 6-week cycles of sunitinib (at a dose of 50 mg given orally once daily for 4 weeks, followed by 2 weeks without treatment) versus interferon alfa (at a dose of 9 MU given subcutaneously three times weekly).	patients with previously untreated, metastatic renal-cell carcinoma	

continued...

Trial	Treatments	Patients	Trials design and methods
pazopanib vs placebo			
Sternberg , 2010 n=NA follow-up:	pazopanib versus placebo	treatment-naive and cytokine-pretreated patients with advanced renal cell carcinoma	Parallel groups double-blind
sorafenib vs placebo			
Ratain , 2006 n=NA follow-up:	-	patients with metastatic renal cell carcinoma	
axitinib vs sorafenib			
Qin , 2012 n=NA	-	-	
sunitinib vs sorafenib			
SWITCH [NCT00732914] n=NA	-	-	
tivozanib vs sorafenib			
TIVO-1 , 2013 [NCT01030783] n=260/257 follow-up:	tivozanib versus sorafenib	initial targeted therapy in patients with metastatic renal cell carcinoma	
pazopanib vs sunitinib			
COMPARZ , 2013 [NCT00720941] n=557/553 follow-up:	continuous dose of pazopanib (800 mg once daily) versus sunitinib in 6-week cycles (50 mg once daily for 4 weeks, followed by 2 weeks without treatment)	patients with clear-cell, metastatic renal-cell carcinoma, first line	Parallel groups

References

Powles, 2014:

Disruptor-1, :

Escudier, 2009:

Escudier B, Szczylik C, Hutson TE, Demkow T, Staehler M, Rolland F, Negrier S, Laferriere N, Scheuring UJ, Cella D, Shah S, Bukowski RM Randomized phase II trial of first-line treatment with sorafenib versus interferon Alfa-2a in patients with metastatic renal cell carcinoma. J Clin Oncol 2009;27:1280-9 [19171708]

Motzer, 2007:

Motzer RJ, Hutson TE, Tomczak P, Michaelson MD, Bukowski RM, Rixe O, Oudard S, Negrier S, Szczylik C, Kim ST, Chen I, Bycott PW, Baum CM, Figlin RA Sunitinib versus interferon alfa in metastatic renal-cell carcinoma. N Engl J Med 2007;356:115-24 [17215529]

Cella D, Li JZ, Cappelleri JC, Bushmakin A, Charbonneau C, Kim ST, Chen I, Motzer RJ, Quality of life in patients with metastatic renal cell carcinoma treated with sunitinib or interferon alfa: results from a phase III randomized trial. J Clin Oncol 2008;26:3763-9. [18669464] 10.1200/JCO.2007.13.5145

Motzer RJ, Hutson TE, Tomczak P, Michaelson MD, Bukowski RM, Oudard S, Negrier S, Szczylik C, Pili R, Bjarnason GA, Garcia-del-Muro X, Sosman JA, Solska E, Wilding G, Thompson JA, Kim ST, Chen I, Huang X, Figlin RA, Overall survival and updated results for sunitinib compared with interferon alfa in patients with metastatic renal cell carcinoma. J Clin Oncol 2009;27:3584-90. [19487381] 10.1200/JCO.2008.20.1293

Sternberg, 2010:

Sternberg CN, Davis ID, Mardiak J, Szczylik C, Lee E, Wagstaff J, Barrios CH, Salman P, Gladkov OA, Kavina A, Zarb JJ, Chen M, McCann L, Pandite L, Roychowdhury DF, Hawkins RE Pazopanib in locally advanced or metastatic renal cell carcinoma: results of a randomized phase III trial. J Clin Oncol 2010;28:1061-8 [20100962]

Ratain, 2006:

Ratain MJ, Eisen T, Stadler WM, Flaherty KT, Kaye SB, Rosner GL, Gore M, Desai AA, Patnaik A, Xiong HQ, Rowinsky E, Abbruzzese JL, Xia C, Simantov R, Schwartz B, O'Dwyer PJ Phase II placebo-controlled randomized discontinuation trial of sorafenib in patients with metastatic renal cell carcinoma. J Clin Oncol 2006;24:2505-12 [16636341] 10.1200/JCO.2005.03.6723

Qin, 2012:

SWITCH, :

Calvani N, Morelli F, Leo S, Orlando L, Lombardi L, Gnoni A, Cinefra M, Maiello E, Lorusso V, Cinieri S Sequential use of sorafenib and sunitinib in advanced renal cell carcinoma: does the order of sequencing matter? Med Oncol 2012;29:1908-13 [21858552]

TIVO-1, 2013:

Motzer RJ, Nosov D, Eisen T, Bondarenko I, Lesovoy V, Lipatov O, Tomczak P, Lyulko O, Alyasova A, Harza M, Kogan M, Alekseev BY, Sternberg CN, Szczylik C, Cella D, Ivanescu C, Krivoshik A, Strahs A, Esteves B, Berkenblit A, Hutson TE Tivozanib versus sorafenib as initial targeted therapy for patients with metastatic renal cell carcinoma: results from a phase III trial. J Clin Oncol 2013;31:3791-9 [24019545] 10.1200/JCO.2012.47.4940

COMPARZ, 2013:

Motzer RJ, Hutson TE, Cella D, Reeves J, Hawkins R, Guo J, Nathan P, Staehler M, de Souza P, Merchan JR, Boleti E, Fife K, Jin J, Jones R, Uemura H, De Giorgi U, Harmenberg U, Wang J, Sternberg CN, Deen K, McCann L, Hackshaw MD, Crescenzo R, Pandite LN, C Pazopanib versus sunitinib in metastatic renal-cell carcinoma. N Engl J Med 2013;369:722-31. [23964934] 10.1056/NEJMoa1303989

4 VEGFR, MET AXL TKI

Trial	Treatments	Patients	Trials design and methods
cabozantinib vs sunitinib			
CABOSUN , 2017 [NCT01835158] n=79/78 follow-up:	cabozantinib (60 mg once per day) versus sunitinib (50 mg once per day; 4 weeks on, 2 weeks off).	untreated clear cell mRCC and Eastern Cooperative Oncology Group performance status of 0 to 2 and were intermediate or poor risk per International Metastatic Renal Cell Carcinoma Database Consortium criteria	Parallel groups open-label

References

CABOSUN, 2017:

Choueiri TK, Halabi S, Sanford BL, Hahn O, Michaelson MD, Walsh MK, Feldman DR, Olencki T, Picus J, Small EJ, Dakhil S, George DJ, Morris MJ Cabozantinib Versus Sunitinib As Initial Targeted Therapy for Patients With Metastatic Renal Cell Carcinoma of Poor or Intermediate Risk: The Alliance A031203 CABOSUN Trial. J Clin Oncol 2017;35:591-597 [28199818]

5 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.

TrialResults-center is non-profit and self-funded.