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TARIBO trial: Cytoreductive nephrectomy in metastatic renal cell carcinoma patients treated with targeted agents

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Abstract #182564

TARIBO trial: Cytoreductive Nephrectomy in Metastatic Renal Cell Carcinoma Patients Treated with Targeted Agents.

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Abstract Text:

Background: In the cytokine era cytoreductive nephrectomy (CN) has been shown to increase survival in patients (pts) with metastatic renal cell carcinoma (mRCC). Efficacy of tyrosine kinase inhibitors (TKIs), including first-line sunitinib and pazopanib has been demonstrated. It is unclear if similar survival benefit could be achieved without CN with TKIs since most of pts enrolled into phase III trials had undergone CN

Methods: A total of 270 mRCC pts will be randomized to receive CN followed by TKIs vs upfront TKIs without CN. Patients will receive pazopanib 800 mg orally daily or sunitinib 50 mg daily, 4 weeks on/ 2 weeks off. The choice of TKI will be done according to investigator's clinical practice. Primary objective: to compare clinical benefit, as measured by overall survival (OS), provided by CN followed by TKIs vs upfront TKIs in pts with mRCC. Secondary objectives: i) to compare clinical benefit, as measured by progression-free survival (PFS) and response rate (RR) provided by CN followed by TKIs vs upfront TKIs; ii) Safety; iii) Exploratory analyses: evaluation of the predictive role of circulating tumor cells count and circulating tumor DNA at baseline, before and after surgery (in pts undergoing CN), 24 weeks after randomization and at the time of disease progression

Key inclusion criteria: Favorable or intermediate MSKCC or Heng prognostic risk group; histological diagnosis of RCC with a clear-cell component; resectable asymptomatic mRCC with primary tumor in place; up to three different metastatic sites; ≥ 3 metastatic lesions

Key exclusion criteria: Widespread disease ($>$ or $= 4$ metastatic organ sites); disease suitable of metastasectomy (< 3 lesions confined at one organ site)

Statistical plan: the sample size was calculated in order to compare 5-year OS between subjects randomized to receive CN followed by TKIs and those randomized to receive upfront TKIs. A total of 191 deaths will yield 80% power to detect a hazard ratio of 1.5 of upfront TKIs vs CN followed by TKIs with an overall type 1 error of 0.05 (two-sided log-rank test). Such a HR corresponds to an increase in the 5-year OS, from an anticipated value of 10% for TKIs to 21.5% for CN followed by TKIs. To date 10/270 pts have been enrolled

Title:

TARIBO trial: Cytoreductive Nephrectomy in Metastatic Renal Cell Carcinoma Patients Treated with Targeted Agents.

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Is this a late-breaking data submission?

No

Is this abstract a clinical trial?

Yes

Is this clinical trial registered?

Yes

Registry Name:

Clinicaltrials.gov

Registration Number:

NCT02535351

Research Funding Source:

Other Foundation

Research Funding Source Name:

Associazione Italiana Ricerca sul Cancro

Have the data in this abstract been presented at another major medical meeting?

Yes

Meeting:

ASCO annual meeting 2016

Updates to Data:

Recruiting has started

Has this research been submitted for publication in a medical journal?

No

Type of Research:

Biomarker

Research Category:

Clinical

Continued Trial Accrual:

Yes

Received Grant funding:

No

Relevant to geriatric oncology:

Yes

Sponsor:

Giuseppe Procopio, MD

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