SGCs are rare and heterogenous tumors (<1% of all malignancies in Europe). Among more than 20 histotypes, only salivary duct carcinoma (SDC) and adenocarcinoma NOS expresses AR. These variants are aggressive and associated with poor prognosis. Surgery is the main curative treatment but upon relapse, patients are left with very few options. There is an urgent need to understand their biology to enable progress in this rare disease.

Identification of AR as a target for new treatment strategies in SGC can be practice changing. This academic study to explore new treatment options in SGC is an important step forward.

This study aims to evaluate the efficacy and safety of ADT (experimental arm) vs chemotherapy (standard arm) in patients with recurrent and/or metastatic, AR expressing SGC, by demonstrating a 15% improvement in PFS rate at 6 months in favor of ADT. Mechanisms of AR activation and resistance will be studied.

STUDY DESIGN

In this multicenter, randomized, phase II intergroup study, a total of 76 treatment naive patients (Cohort A) are planned to be randomized to receive ADT or platinum-based chemotherapy. Previously treated patients will be enrolled in a separate Cohort B to receive ADT. Patients from Cohort A randomized to chemotherapy can enter Cohort B at disease progression.

Primary endpoint for cohort A is progression free survival according to RECIST 1.1 and/or POWG2 v.2007 for bone lesions, or death, whichever comes first. Primary endpoint for cohort B is best overall response according to RECIST 1.1. Combined score: 3+ (high intensity); 3+ (low intensity).

STUDY ENDPOINTS

Score for AR staining:

- 0: < 10% - 1:
- ≥ 10% to < 30% - 2:
- ≥ 30% to < 70% - 3:
- ≥ 70% - 4:

AR negative: 0
AR positive: 1

Tea cut with a large nest and discohesive neoplastic cells. Strongly positive for AR (score 6).

AR-negative adenocarcinoma NOS (low expression)

SDC staining AR (immunoreactivity)

SDC AR positive

Combined score: 3+ (high intensity); 3+ (≥ 70% of positive nuclei) = 6+ (high expression).

CONCEPT OVERVIEW

STUDY STATUS

As of 09 August 2017:

Number of patients registered = 41
Number of patients centrally assessed = 40
Number of patients enrolled (AR positive patients) = 22
Number of AR negative patients = 6
Number of screening failures/pending central review = 15

STUDY DESIGN

4 weeks washout period - enrollment

CONSORT (1) - randomization

ClinicalTrials.gov: NCT01969578

OBJECTIVES

ASSESSMENT OF AR EXPRESSION

Detection: EnVision Flex (μmouse) High-Link kit (Dako), mouse monoclonal primary antibody anti-androgen receptor (RCP clone AA441), Dako; code M3462 antibody incubation 30 minutes at room temperature.

Score for AR staining:

- 0: < 10% - 1:
- ≥ 10% to < 30% - 2:
- ≥ 30% to < 70% - 3:
- ≥ 70% - 4:

AR negative: 0
AR positive: 1

Score for AR staining:

- 0: < 10% - 1:
- ≥ 10% to < 30% - 2:
- ≥ 30% to < 70% - 3:
- ≥ 70% - 4:

AR negative: 0
AR positive: 1

only the high expressers will be enrolled in the trial (AR expression level of 6 in nach of neoplastic cells).


Poster #1106 Tip

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