CENTER FOR SURGICAL SCIENCE

REGION SJÆLLAND
SJÆLLANDS UNIVERSITETSHOSPITAL
- vi er til for dig

The Department of Surgery, Zealand University Hospital

Lykkebækvej 1
4600 Køge
Denmark

E-mail: igo@regionsjaelland.dk

www.regionsjaelland.dk

EudraCT number: 2020-004623-17

Sponsor's protocol code number: 26092020

Full title of the trial: Irreversible electroporation in combination with immune checkpoint inhibition, in patients with metastatic pancreatic cancer - A prospective, phase 2 study

Justification for early termination of the trial

The premature termination of the study was decided due to 19 SAEs in nine patients, of which 14 were seen in the seven patients that were treated with irreversible electroporation and nivolumab. The two patients that did not receive any treatments died within two months of the inclusion date. Seven out of seven treated patients died within eight months after the inclusion date. All deaths have been related to the course of the metastatic pancreatic cancer. Two SARs related to nivolumab were seen including an infusion related reaction and an immune system disorder (suspicion of hepatitis/ cholangitis/immune-related toxicity). In the seven treated patients, SAEs included two thromboembolic events, two strokes, fall, pleura effusion, and reduced general health condition. No complications to the treatment with irreversible electroporation were seen.

In six out of seven a 2-months CT response evaluation per RECIST criteria were done. Showing stable disease in one patient and progressive disease in five patients. One patient did not undergo CT response evaluation, due to an infusion-related reaction to nivolumab and rapid, clinically assessed, progression of the disease. The patient with stable disease at 2-months CT evaluation, did not undergo any more CT evaluations as the patient was excluded from the study, due to a case of hepatitis or cholangitis.
The median overall survival in the seven treated patients were 3.6 months (range, 2.4-7.9 months). In the intention-to-treat analysis the median OS was 2.7 months (range, 1.5-7.9).

To sum up, based on the large number of SAEs, no signs of efficacy seen in the included patients, and no expectations to see any clinical benefit of the treatment in the remaining patients to be included nor moving forward, it was decided to terminate the trial prematurely after thorough considerations in the multidisciplinary team of investigators.

Sponsor

Date and signature: 12/4-24

Print name: Ismail Gögenur