

2486R0

Towards organ preservation and cure via immunotherapy in cutaneous squamous cell carcinoma patients, normally undergoing extensive curative surgery and radiotherapy (MATISSE 2)

S.W. Van Dijk¹, J.P. De Boer², M. Klop³, B.M. Tijink⁴, L. Devriese⁵, R. De Bree⁴, J.B.A.G. Haanen⁶, C. Zuur⁷

¹ Department of Head And Neck Surgical Oncology, NKI-AVL - Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands, ² Medical Oncology Dept, NKI-AVL - Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands, ³ Head and surgery and oncology, NKI-AVL - Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands, ⁴ Department of Head And Neck Surgery, UMC - University Medical Center Utrecht, Utrecht, Netherlands, ⁵ Huispostnummer Q05.4.300 - Cancer Center Medische Oncologie, UMC-University Medical Center Utrecht, Utrecht, Netherlands, ⁶ Department of Medical Oncology, NKI-AVL - Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands ⁷ Head and Neck Surgery Dept., NKI-AVL - Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands

Background

The MATISSE trial (NCT04620200) showed that 80% of patients with a cutaneous squamous cell carcinoma (CSCC) and an indication for extensive curative surgery with or without adjuvant radiotherapy as standard of care (SOC) reached a partial or major pathological response following two courses of neoadjuvant nivolumab and ipilimumab (NIVO/IPI). In addition, 9 patients reached a clinical complete remission (CCR) after only two courses of NIVO/IPI, without SOC. This raised the question whether organ preservation and cure can be reached via only ultra-short neoadjuvant NIVO/IPI, without SOC and without maintenance immunotherapy.

Methods

In the MATISSE 2 trial (NCT06823479), 41 CSCC patients with an indication for extensive or disfiguring curative surgery will be treated with neoadjuvant NIVO (weeks 0 & 2) and IPI (only week 0). Response evaluation is performed in week 5. In case of a non-response, patients undergo SOC in week 6. In case of a clinical response following NIVO/IPI, we will withhold SOC and patients enter a strict wait-and-monitoring programme.

Results

So far, thirty-one patients have been included (median follow-up of 8 months). Overall, 22/31 (71%) patients showed a clinical response in week 5 and did not undergo SOC per protocol, of whom 15/31 (48%) achieved a CCR and 7/31 (23%) achieved a partial clinical response (PCR) during their wait-and-monitoring program. In total 9/31 (29%) patients received SOC, of whom one patient showed a complete pathological response in the surgical specimen. Immune-related toxicity (19% grade 3-4) was well manageable. There was no delay in surgery due to immune-related toxicity.

Conclusions

Overall, 71% of patients reached a clinical response and did not undergo surgery. So far, 48% of patients reached a CCR following only ultra-short neoadjuvant NIVO/IPI, without SOC and without maintenance immunotherapy. Longer follow-up is required to investigate further deepening of the response in PCR patients and the durability of the response in CCR patients.

Clinical trial identification

NCT06823479 EU trial nr 2024-516152-17-00.

Legal entity responsible for the study

NKI-AVL.

Funding

Private foundations.

Disclosure

J.B.A.G. Haanen: Financial Interests, Institutional, Advisory Board: Bristol Myers Squibb, Achilles Therapeutics, Immunocore, Gadeta, Ipsen,

Merck Sharpe & Dohme, Merck Serono, Pfizer, Molecular Partners, Novartis, Roche, Sanofi, Instil Bio, Iovance Biotherapeutics, AstraZeneca; Financial Interests, Institutional, Advisory Board, SAB member: BioNTech, PokeAcell, T-Knife; Financial Interests, Personal, Advisory Board, SAB member: Neogene Therapeutics, Sastra Cell Therapy; Financial Interests, Personal, Advisory Board: Third Rock Venture, Scenic, CureVac, Imcyse; Financial Interests, Personal, Stocks/Shares: Neogene Therapeutics, Sāstra; Financial Interests, Institutional, Research Grant: Bristol Myers Squibb, BioNTech US, Merck Sharpe & Dohme, Amgen, Novartis, Asher Bio, Sastra Cell Therapy; Non-Financial Interests, Member: ASCO, AACR, SITC; Other, Other, Editor-in-Chief IOTech: ESMO; Other, Other, Editorial Board ESMO Open: ESMO; Other, Other, Editorial Board: Kidney Cancer. All other authors have declared no conflicts of interest.

© *European Society for Medical Oncology*