

# IMMUNE-MEDIATED HEPATITIS SECONDARY TO TREATMENT WITH PEMBROLIZUMAB. A CASE REPORT

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## BACKGROUND AND IMPORTANCE

Immune-mediated reactions play a major role in the immunotherapy, so it is important monitoring and follow-up to improvement safety patient.

## AIM AND OBJECTIVES

To describe a case of immune-mediated hepatitis secondary to the use of pembrolizumab and multidisciplinary intervention in its management.

## MATERIAL AND METHODS

- ✓ A 81-year-old patient with advanced amelanotic nodular melanoma, with lung and axillary metastasis.
- ✓ Data obtained → digital medical record and chemotherapy electronic prescription program.
- ✓ Review → Safety profile of pembrolizumab in its technical data sheet (TDS) and the literature reported cases of hepatobiliary disorders with pembrolizumab.

## RESULTS

1º → Pembrolizumab 200 mg/3weeks

3ª infusion

Regular general condition, asthenia and dysgeusia, ↑transaminases (ASP: 31U/L; ALT: 130U/L) and total bilirubin: 1.60 mg/dL

2º → Immunosuppressive treatment

Patient asymptomatic and grade 1 immune-mediated hepatitis

3º



switching

Nivolumab 240 mg twice weekly



Grade 4 immune-mediated hepatitis

- Pharmacist performed a review of the TDS and literature that confirmed the event (hepatitis is described as a frequent AE (≥ 1/100 to < 1/10)).
- AE notified to the Spanish Pharmacovigilance System → Naranjo Algorithm → **Score 5: probable relationship (drug ↔ AE)**.
- Immune-mediated hepatitis is an AE described with nivolumab, which was well tolerated.

## CONCLUSION AND RELEVANCE



Close monitoring and follow-up of AEs associated with drugs is important, as the participation of the pharmacist in multidisciplinary teams, validating treatments and carrying out their monitoring. All of this contributes to an improvement in the management of AEs and in patient safety.