and access timelines of biotechnological products, shows that biosimilars have been launched to patients access with reimbursement much faster than biotechnological products.

PP153 Efficacy And Safety of Onasemnogene Abeparvovec For The Treatment Of Patients With Spinal Muscular Atrophy Type 1: Meta-Analysis

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Introduction: Onasemnogene abeparvovec has been approved for the treatment of spinal muscular atrophy 5q (SMA) type 1 in several countries, which calls for an independent assessment of its evidence regarding efficacy and safety.
Methods: This study results from searches conducted on databases MEDLINE, Embase, LILACS and Cochrane Library up to November 2022, supported by additional searches on registry databases and by manual searches of references listed in eligible studies. Outcomes of interest were global survival and mechanical-ventilation-free survival, improvement in motor function and treatment-related adverse events. Risk of bias was assessed via ROBINS-I and certainty of evidence via GRADE. Proportional meta-analysis models were performed when applicable.
Results: Four reports of three open-label, non-comparative clinical trials (START, STR1VE-US and STR1VE-EU) covering 67 patients were included in review. Meta-analyses of data available in a 12-month follow-up estimate a global survival of 97.6% (95% confidence interval [CI]: 92.6, 99.9; I2 = 0%, n=67), an event-free survival of 96.5% (95%CI: 90.8, 99.5; I2 = 32%, n=66) and a CHOP-INTEND score of 40 points or less proportion of 87.3% (95%CI: 69.8, 97.8; I2 = 69%, n=67). Proportions of 61.1% (95%CI: 40, 80.2; I^2 = 62%, n=67) of serious adverse events and of 58.4% (95%CI: 46.5, 69.8; I2 = 78%, n=67) of treatment-related adverse events are estimated. Despite the significant effect magnitude, reviewed studies were assessed as high risk of bias and as having very low certainty of evidence due to imprecision and risk of bias.
Conclusions: Reduced sample size and follow-up time offer uncertainties as regards the long-term benefits of the gene therapy, which strongly calls for the monitoring and assessment of results in clinical practice.

PP155 Should Breast Cancer Patients Avoid Venipuncture In The Ipsilateral Arm? A Rapid Review Of The Evidence

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Introduction: This rapid review clarified the evidence supporting avoidance of venipuncture on the ipsilateral arm in breast cancer patients who have had sentinel lymph node biopsy (SLNB) or axillary lymph node clearance (ALNC), as a preventive measure against lymphoedema.
Methods: A systematic search was carried out for systematic reviews with the following elements:

- Population – breast cancer patients who had SLNB or ALNC
- Intervention – avoidance of venipuncture in the ipsilateral arm
- Comparator –use of either arm for venipuncture
- Outcomes – risk of lymphoedema in the ipsilateral arm

Databases searched included PubMed (MEDLINE), Epistemonikos and the Cochrane Database of Systematic Reviews. Included reviews were critically appraised with the AMSTAR2 instrument and the primary studies were extracted and tabulated in a narrative synthesis.
Results: Six reviews were included; none of the reviews self-identified as systematic reviews in their titles/abstracts. Four reviews did report methods, including systematic search strategies and describing studies in adequate detail. However, all reviews did not meet most criteria on the AMSTAR2 checklist. The reviews concluded that the evidence base for avoiding venipuncture was inconsistent. An evidence table was consequently drawn up of the primary studies included in the reviews as a narrative synthesis of the primary evidence base.
The primary evidence base comprised 12 observational studies – six prospective cohort or descriptive studies and 6 retrospective studies. These studies were inconsistent and inconclusive; studies that found an association or reported cases following ipsilateral venipuncture were subject to recall bias or other potential confounders. Guidelines or patient information recommending avoidance of ipsilateral venipuncture do so based on expert opinion rather than consistent findings from empirical studies.
Conclusions: All reviews concluded that the evidence base for avoiding venipuncture was inconsistent. Review authors consistently recognized there was no strong basis for the prevalent recommendations to avoid ipsilateral venipuncture to prevent lymphoedema. Such recommendations lead to unnecessary measures that may be detrimental to patients. Stakeholders should reconsider advice to patients in the light of existing evidence and weigh up the uncertain benefits against potential harm to patients.

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