Recommendations for improving the quality of reporting clinical electrochemotherapy studies based on qualitative systematic review

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CHECKLIST

Recommendations and minimal requirements for reporting clinical trial results on electrochemotherapy (key elements)

Trial design:
☐ Explanation of the rationale of the study
☐ Description of trial design and sponsorship
☐ Indication of trial endpoints
☐ Indication of inclusion and exclusion criteria
☐ Trial approval and registration
☐ Informed consent statement

Patient population:
☐ Patient demographic data (in tabular form)
☐ Setting - palliative or curative
☐ Tumor histology
☐ Disease stage (lymph node or visceral metastases)
☐ Description of target lesions treated with electrochemotherapy (anatomical location, number and size )
☐ Previous local treatments
☐ Concomitant oncological treatment
☐ Adjuvant and / or following oncological treatments

Treatment information:
☐ Indication of electroporation protocol (adherence to SOP or other)
☐ Type of anesthesia
☐ Drug (producer)
☐ Drug details (dose, concentration, route of administration)
☐ Time interval between drug administration and application of electric pulses

☐ Technical details of the electric pulse generator, including type, manufacturer and version of software, if applicable
☐ Information about the electrodes used, for respective tumor(s)
☐ Number of electric pulses application per tumor
☐ Inclusion of a report on electrical parameters (n, T, U, I, f)*
☐ Adequacy of tumor treatment (treatment application success rate)
☐ Extent of the safety margins treated
☐ Number of treatment sessions (with interval between sessions)
  * Legend: n = number; T = duration of pulses; U = voltage amplitude applied; I = current measured; f = pulse repetition frequency

Treatment outcome assessment:
☐ Time of response assessment
☐ Standardized response evaluation criteria (e.g. WHO, RECIST1.1, mRECIST)
☐ Time to local and systemic disease progression
☐ Standardized toxicity criteria (e.g. CTCAE v4.0)
☐ Quality of Life (QoL), patient reported outcomes (PRO)
☐ Track of patients lost to follow-up

Analysis and interpretation of results:
☐ Summary of trial endpoints
☐ Additional outcome parameters (e.g., QoL, PRO)
☐ Predictive factors
☐ Results interpretation
☐ Future research directions