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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