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
- 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

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

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