

Title	Recommendations for improving the quality of reporting clinical electrochemotherapy studies based on qualitative systematic review
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Publication date	2016-02-16
Original Citation	Campana, L. G., Clover, A. J. P., Valpione, S., Quaglino, P., Gehl, J., Kunte, C., Snoj, M., Cemazar, M., Rossi, C. R., Miklavcic, D. and Sersa, G. (2016) 'Recommendations for improving the quality of reporting clinical electrochemotherapy studies based on qualitative systematic review', 50(1), pp. 1-13. doi: 10.1515/raon-2016-0006
Type of publication	Article (peer-reviewed)
Link to publisher's version	10.1515/raon-2016-0006
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Download date	2023-10-02 09:13:51
Item downloaded from	https://hdl.handle.net/10468/9268



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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