Comment on “Adoptive T-cell therapy for malignant melanoma patients with TILs obtained by ultrasound-guided needle biopsy” by Gustav J. Ullenhag et al.

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Dear Editors,

Gustav Ullenhag and colleagues' publication *Adoptive T-cell therapy for malignant melanoma patients with TILs obtained by ultrasound-guided needle biopsy* from December 2011 (Cancer Immunology, Immunotherapy; DOI: [10.1007/s00262-011-1182-4](https://doi.org/10.1007/s00262-011-1182-4)) put forward some interesting new data bearing on the feasibility of TIL production and treatment when tumor material is obtained by needle biopsy.

However, the paper also raises several questions and concerns; it is published as a clinical study and reports on clinical data but essential information is missing. The authors write that ‘tumor was resected as part of an Ethical Committee approved clinical study’. What does that mean? Was TIL treatment of the patients not included in that approval? Also, no reference is given to approval from the national health authorities and study identification number from clinicaltrials.gov is missing.

According to international agreement, clinical trials should be registered in a public trials registry in order to be

considered for publication. Was this done? It is crucial that all clinical studies fulfill these criteria to ensure that they have been carried out according to the guidelines of GCP including patient and data registration and monitoring. Otherwise clinical data including toxicity and response parameters such as objective responses and response rates remain unvalidated.

In all circumstances, it is absolutely essential that the reader is given sufficient information to be able to assess the quality of the study and validity of data. Unfortunately, in the paper of Ullenhag et al., many required details are missing, for example, trial design, in and exclusion criteria, study endpoints, and intention to treat population, making it impossible for the reader to judge the significance of the reported clinical results.

Conflict of interest I hereby declare that I have no financial conflict of interest.

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