

The ethics of pain clinical trials on persons lacking judgment ability: much to improve.

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Source

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Abstract

AIM:

People lacking judgmental ability (newborn infants [NIs] and persons with mental impairment [PMI]) are reported to receive less analgesic treatments than people who can give adequate informed consent. We performed the present study to assess whether this also happens in clinical trials that should statutorily guarantee basic patients' rights. We examined those trials in which patients undergo painful minor procedures (PMP) because these procedures are frequent and severely stressful for NI and PMI.

MATERIALS AND METHODS:

We performed a Medline search to retrieve the studies published in 2009 and 2010, in which NI and PMI underwent PMP.

RESULTS:

We retrieved 46 studies that exposed NI to PMP; only in 14.2% of the studies, a validated analgesic treatment was administered to the control group. We retrieved only one article where PMP was performed in PMI for clinical reasons (venipuncture); in 13 more studies, pain was experimentally provoked by noxious stimuli such as heat, electricity, or arm mobilization. All these studies were not performed to evaluate a possible analgesic strategy but to assess PMI's pain responsiveness and no analgesia was used.

CONCLUSION:

PMI and NI enrolled in clinical trials as controls rarely receive analgesia; and few studies exist to find out analgesic treatments shaped on PMI's exigencies. These data raise concern about the actual guarantees for persons lacking judgmental ability enrolled in potentially painful trials. We also recommend more effort to find out analgesic treatments tailored to the specific exigencies of PMI.