Author's response to reviews

Title: Safety of intramuscular influenza vaccine in patients receiving oral anticoagulation therapy: a single blinded multi-centre randomized controlled clinical trial

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Classically, we have been recommending to patients receiving oral anticoagulant therapy to avoid the intramuscular administration route due to the supposed risk of secondary effects, such as haemorrhages in the injection area. Because of this, the recommendation of using the subcutaneous administration route with vaccines, specifically the influenza vaccine, has become quite widespread. The recommended administration route of the influenza vaccine is intramuscular and there is data supporting its immunogenicity using this administration route. Besides, it is known that the subcutaneous administration of the vaccine often causes local reactions, sometimes quite annoying. This recommendation of not using the intramuscular route is not supported by any clinical trial. Furthermore, there are three previous studies where the influenza vaccine seems to have no problems with the intramuscular route, but these studies have a small sample.

Currently, the CDC's recommendations are that it is up to the professional to use the intramuscular administration in patients receiving oral anticoagulant therapy, as long as they press for two minutes the point of injection. This recommendation is only supported by a non controlled study in haemophilic patients and with the hepatitis B vaccine.

Our randomized clinical trial contributes to solve these questions showing the local safety of the intramuscular administration of the influenza vaccine in patients receiving oral anticoagulant therapy.