PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Split-mouth and parallel-arm trial to compare pain with intraosseous anaesthesia delivered by the computerized Quicksleeper™ system and conventional infiltration anaesthesia in pediatric oral health care: protocol for randomized controlled trial
AUTHORS	Smail-Faugeron, Violaine; Muller-Bolla, Michèle; Sixou, Jean-Louis; Courson, Frédéric

VERSION 1 - REVIEW

REVIEWER	Javier Ata-Ali Dr. Javier Ata-Ali DDS, MS, MPH, PhD Public Dental Health Service. Arnau de Vilanova Hospital
REVIEW RETURNED	18-Mar-2015

GENERAL COMMENTS	Really I do not have any concern with this study, because this study is well-designed. However I have some advices for this protocol. - For Young children with 7 years old is too dificult to understand and to tell us the visual analogue scale. I think that children with 10-11 years old is a better age. - Many studies have been published with this intraosseous anesthesia technique. A number of authors have found intraosseous anesthesia to be associated with an increase in patient heart rate when the anesthetic solution contains adrenalin or levonordefrin. I think that is a simple, cheap and effective procedure to record the Heart rate, before the injection of the anesthetic solution and again after the injection. - Page 6 line 24. Please add trade names and manufacturer name, city, state, and country, of the topical anesthesia.

REVIEWER	Nikolaos Pandis University of Bern, Switzerland
REVIEW RETURNED	20-Mar-2015

GENERAL COMMENTS	Very well written protocol following the current standards It would be good if authors clarified the block size and if it was variable or not [randomization]

VERSION 1 – AUTHOR RESPONSE

Reviewer Name Javier Ata-Ali
Institution and Country Dr. Javier Ata-Ali DDS, MS, MPH, PhD
Public Dental Health Service. Arnau de Vilanova Hospital

Spain
Please state any competing interests or state 'None declared': None declared

Dear Authors,
Really I do not have any concern with this study, because this study is well-designed.

Answer: We thank the reviewer for his appreciation.
However I have some advices for this protocol.
- For Young children with 7 years old is too difficult to understand and to tell us the visual analogue scale. I think that children with 10-11 years old is a better age.

Answer: We thank the reviewer for his comment.
However, several studies have shown that a visual analogue scale was appropriate for use in assessment of the intensity of children's acute pain from age 5 or 6 onward.
References:
1. Barretto et al. Evaluation of toothache severity in children using a visual analogue scale of faces. Pediatr Dent 2004;26(6):485-91.
2. Shields et al. Predictors of a child's ability to use a visual analogue scale. Child Care Health Dev 2003;29(4):281-90.

- Many studies have been published with this intraosseous anesthesia technique. A number of authors have found intraosseous anesthesia to be associated with an increase in patient heart rate when the anesthetic solution contains adrenalin or levonordefrin. I think that is a simple, cheap and effective procedure to record the Heart rate, before the injection of the anesthetic solution and again after the injection.

Answer: We thank the reviewer for his comment. In our protocol, we use 4% articaine with adrenalin, 1:200,000. Several studies showed that intraosseous delivery by slow speed of injection did not induce significant clinical changes in heart rate (Pereira et al. Articaine (4%) with epinephrine (1:100,000 or 1:200,000) in intraosseous injections in symptomatic irreversible pulpitis of mandibular molars: anesthetic efficacy and cardiovascular effects. Oral Surg Oral Med Oral Pathol Oral Radiol. 2013 Aug;116(2):e85-91; Susi et al. Heart rate effects of intraosseous injections using slow and fast rates of anesthetic solution deposition. Anesth Prog. 2008 Spring;55(1):9-15). Other studies showed that intraosseous anesthesia with 2% lidocaine and 1:100,000 epinephrine induced statistically significant increase in heart rate during solution deposition and for 2 min after the injection (Wood et al. Comparison of intraosseous and infiltration injections for venous lidocaine blood concentrations and heart rate changes after injection of 2% lidocaine with 1:100,000 epinephrine. J Endod. 2005 Jun;31(6):435-8; Bigby et al. Articaine for supplemental intraosseous anesthesia in patients with irreversible pulpitis. J Endod. 2006 Nov;32(11):1044-7). Indeed, for our protocol excluding patients with general disease, this slight increase in heart rate, when it exists, has no impact on the general health for healthy patients.

- Page 6 line 24. Please add trade names and manufacturer name, city, state, and country, of the topical anesthesia.

Answer: We added trade names and manufacturer name, city, state, and country, of the topical anesthesia.

Revised Methods section, page 7: “Xylocaïne® visqueuse 2% (AstraZeneca, Rueil Malmaison, France)”

Reviewer Name Nikolaos Pandis
Institution and Country University of Bern, Switzerland
Please state any competing interests or state ‘None declared’: None declared

Very well written protocol following the current standards
Answer: We thank the reviewer for his appreciation.
It would be good if authors clarified the block size and if it was variable or not [randomization]

Answer: We thank the reviewer for his comment. In the revised manuscript, we clarified that the block size was variable. In fact, we used a permuted block design with a computer random number generator. There are two block sizes and the block sizes were randomly varied. We prefer no to report the block sizes so that trialists do not become aware of that information.
Revised Methods section, page 9: “We will use a computer-generated, permuted-block randomization sequence for anaesthesia allocation with two block sizes randomly varied.”

VERSION 2 – REVIEW

REVIEWER	Javier Ata-Ali Dr. Javier Ata-Ali DDS, MS, MPH, PhD Public Dental Health Service. Arnau de Vilanova Hospital
REVIEW RETURNED	04-Jun-2015

GENERAL COMMENTS	Thanks for the corrections and thorough revision that you have undertaken. I recommend the acceptance of this study for publication.

REVIEWER	Nikolaos Pandis University of Bern Switzerland
REVIEW RETURNED	06-Jun-2015

GENERAL COMMENTS	I am satisfied with the revisions and recommend for this manuscript to be accepted for publication