- Official title: The effect of warm saline irrigation on the amount of bleeding in impacted mandibular third molar surgery: a split-mouth double-blinded randomized clinical trial
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Study Protocol and Statistical Analysis Plan

To meet the objectives of this split-mouth double-blinded randomized controlled clinical trial, 20 patients who were candidates for bilateral surgical extractions of mandibular third molars were chosen. The participants were selected based on their attendance in the Department of Oral and Maxillofacial Surgery of Tehran University of Medical Sciences, Tehran, Iran from October to December 2017. The sample size was defined to obtain test powers greater than 95% ($\alpha$ = 0.05, $\beta$ < 0.05).

Patients were enrolled in this study voluntarily, and the details on the study design were explained to them prior to signing the informed consent agreement. The study design was approved by the Institutional Review Board of Tehran University of Medical Sciences, according to the principles of the Helsinki declaration (thesis #6234) and was registered in https://clinicaltrials.gov (Code: NCT04143373).

The Inclusion and Exclusion criteria were defined as follows:

Inclusion criteria

- Being a candidate for bilateral mandibular third molar surgery
- Both mandibular third molars must have a similar inclination to the second molar
- Both mandibular third molars must have same Pell & Gregory's classification, indicating the similar surgical difficulty on both sides.

Exclusion criteria

- Presence of any systemic condition or using any type of medication

- History of allergy to local anesthetic (LA) solutions
- Patients with an active gag reflex, because they are more susceptible to swallow the irrigation solution.
- Pregnant and post-menopause women
- Patients with pericoronitis or any local inflammation

Since it is easier and less time-consuming for the right-handed surgeon to extract the impacted molar on the right side, all surgeries were performed by one right-handed oral and maxillofacial surgeon. For each patient, the control and the experimental sides were chosen by a table of random numbers. The surgeon was aware of the experimental side, however the outcome assessor who checked the amount of suctioned solution, and the data analyst were blind. In the control side and the experimental side, $25\pm2^{\circ C}$ and $37\pm1^{\circ C}$ saline were used for irrigation, respectively. All other variables such as the flap type, number, and type of LA cartridges and suturing method were matched between both sides in each patient.

The total time needed for surgery was measured from the moment of the LA injection until the end of suturing. For each patient only 2 cartridges of lidocaine 2% along with 1:100000 epinephrine were used to block the inferior alveolar (direct technique), lingual and long buccal nerves. The timespan between LA injection and the start of surgery was relatively the same. In case the surgery on one side took a relatively longer time, that case would have been excluded.

The amount of saline for irrigation was precisely measured and patients were asked to prevent swallowing till the end of surgery so that all the solutions and debris were suctioned from the oral cavity. In case the volume of irrigation solution was different between control and experimental sides, compensative amount of saline was poured into the mouth and suctioned to balance the amount of suctioned solutions. Also, it was presumed that in healthy patients who were not on any medications, salivary secretion rates were almost the same between surgeries, so that the difference between the volumes of suctioned solutions were due to the differences in bleeding.

The SPSS (Version 23.0, IBM Corp., 2015, New York, USA) and Independent sample T-test were used to analyze the findings.