The Effect of Auricular Position on Measurement Values and Comfort in Measuring Body Temperature by Tympanic Way in Pediatric Patients

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STUDY PROTOCOL

Name of the Project: The Effect of Auricular Position on Measurement Values and Comfort in Measuring Body Temperature by Tympanic Method in Pediatric Patients

The Medical Condition or Disease Being Investigated: The focus of the clinical research is to examine whether there is a difference in body temperature measurements with or without positioning the auricle in the measurements made with a tympanic membrane thermometer in pediatric patients aged 3-17, and to examine the effect of positioning the ear on comfort behaviors.

Research Product / Method: The method of the research is quantitative research. It is based on numerical data by measuring the effect of auricular position on body temperature measurement values and comfort in measurements made with a tympanic membrane thermometer in pediatric patients.

Placebo: No placebo was used in the study.

Arms-Interventions: Previous studies; Uslu et al. (2011), while collecting data; it will be applied to the right ear in the supine position between 08:00-12:00 in the morning, ensuring the room temperature is 22–26°C and the humidity is 30–60%. The first group will consist of pediatric patients whose body temperature is measured without first pulling the auricle and then by pulling it, and the second group will be pediatric patients whose body temperature is measured without pulling the auricle first. When the patient is placed in the supine position, the probe will be placed after positioning the auricle. Care will be taken that the pediatric patient does not lie on the ear at least 15 minutes before the temperature measurement process (Doğdu, 2017). In Oğuz et al.'s (2018) study comparing axillary and tympanic thermometer measurement values in the 0-17 age group, it is recommended to calibrate tympanic thermometers and confirm the measurement with an axillary thermometer. In this direction, the Braun IRT-6520 ear thermometer, which was purchased new by the researcher to be used only for this research, was calibrated on January 2022, the production date, and was not used. The cost of this thermometer was covered by the researcher, and no contact was made with the company. The reason for choosing this product is that it has the Age Precision feature that allows the measurement in accordance with the research sample (0-3 months, 3-36 months, greater than 36 months), visual and auditory warning system (to prevent the temperature measurement from being terminated early / to show that the measurement has been done successfully). signal sound and the light is constantly on for 3 seconds.

Braun ThermoScan LF40 Filters, Patient Data Collection Form, Visual Analogue Scale (VAS) and Comfort Daisies will be used in our research. The comfort of the patients during the measurement will be evaluated using the Visual Analogue Scale (VAS) and Comfort Daisies.

This research will be carried out to determine the effect of placing the auricle position while measuring body temperature by the tympanic route in the measurements of pediatric patients aged 3-17 years, on the body temperature measurement value and the comfort of the patients.

Hypotheses:

H0: There is no significant difference between the body temperature measurement value, VAS score and comfort score performed without pulling the auricle, and the body temperature measurement value, VAS score and comfort score performed by pulling the auricle.

H1: There is a significant difference between the comfort behavior score in the measurement made without pulling the auricle and the comfort behavior score in the measurement made by pulling the auricle.

H2: There is a significant difference between the body temperature measurement value made without pulling the auricle and the body temperature measurement value made by pulling the auricle in patients.

Comparison Hypothesis:

H0: The body temperature measurement value without pulling the auricle, the body temperature measurement value made by pulling the auricle, the VAS score and the comfort score do not differ significantly according to socio-demographic characteristics (age, gender, etc.) and environment.

H1: In patients, the body temperature measurement value without pulling the auricle, the body temperature measurement value made by pulling the auricle, the VAS score and the comfort score show significant differences according to socio-demographic characteristics (age, gender, etc.) and environment.

Research Design: The research was planned as a randomized controlled experimental study. It will be used in the master thesis.

Pediatric patients in the first group whose body temperature was measured without first pulling the auricle and then pulling it out. In the second group, pediatric patients whose auricle was pulled first and then body temperature was measured without pulling.

A computer-assisted randomization program (randomizer.org) will be used to determine the randomization groups (2 groups).

Volunteer Group:

Volunteer group planned to be included in the study:

- Receiving inpatient care/treatment in the Pediatric Intensive Care Clinic

- For the pediatric patient, the parents' willingness to participate in the study

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Volunteer Age Range: 3-17 years old pediatric patients

Number of Volunteers: The population of the research will be the patients hospitalized in Sarıyer Hamidiye Etfal Training and Research Hospital Pediatric Intensive Care Clinic. The sample is; it is planned to consist of 68 pediatric patients who met the sampling criteria and accepted to participate in the study.

Inclusion Criteria:

1) Being between the ages of 3-17

2) Receiving inpatient care/treatment in the Pediatric Intensive Care Clinic

3) For the pediatric patient, the parents' willingness to participate in the study

Exclusion Criteria:

1)Being outside the age range of 3-17

2) Patient's medical condition;

- Being sedated or unconscious,
- Being intubated or tracheostomized,
- Have had a head injury,
- Have an ear disease, have an trauma/surgery,
- Have an ear discharge, ear infection,
- Have sepsis.

3) Implementation of interventions/treatments that will affect the measurement;

- Application of treatment (drops) by ear,
- Last antipyretic treatment taken before 4 hours,
- Before and during body temperature measurement, interventions (hot and cold application, blood transfusion, hemodialysis and plasma exchange) that will affect the measurement

Evaluation of Results: The difference between body temperature measurement values and comfort behavior scores made with and without positioning the auricle will be considered clinically significant.

Statistical Analysis: SPSS v26.0, one of the statistical programs, will be used in the study. Descriptive statistics such as frequency, percentage, arithmetic mean, standard deviation, minimum and maximum will be used in the analysis of the data. Kolmogorov-Smirnov test, one of the normality distribution tests, will be used in the analysis of the data, and parametric tests will be used when the normality assumptions are provided as a result of the analysis. The dependent sample t-test will be used to evaluate the differences of the binary dependent variables, and the independent sample t-test will be used to compare the means of two independent groups. Pearson correlation coefficient will be calculated in the correlation analysis of the scales. All test results will be evaluated at the 0.05 significance level.

Vulnerable Subjects: In the informed consent form prepared for the parents or legal guardian (legal representative), there is the statement "your child will be informed about this research in a way he/she can understand and his/her consent will be obtained for participation in the research". Signatures for informed consent will be obtained from literate children.

Privacy: Personal information obtained from volunteers will be kept confidential.

Payment to Volunteers: Volunteers will not be paid.

Ethical Situation: This study were examined by University of Health Sciences Sisli Hamidiye Etfal Training and Research Hospital Health Practice and Research Center Clinical Research Ethics Committee and it was decided with 3631 number by a majority of votes that there was no ethical objection.