# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Nov 2026

## The investigation of the intravenous dexamethasone’s effect on the duration of analgesia in pregnant patients undergoing spinal analgesia with opioid (Sufentanil) for Normal Vaginal Delivery (NVD)

## Protocol summary


**Study aim**

Assessing the impact of intravenous dexamethasone on analgesia duration from spinal opioids (sufentanil) in pregnant women during vaginal delivery

**Design**

This is a randomized, double-blind clinical trial conducted on 120 multiparous pregnant women. The design includes two control and intervention groups of 60 people.

**Settings and conduct**

Multiparous pregnant women (second to fifth pregnancies) who are candidates for natural vaginal delivery (NVD) and meet the necessary conditions for spinal analgesia are divided randomly into two groups. Only the physician performing the procedure knows the grouping of patients for the procedures, and the person evaluating the patients and the data analyst are not aware of the type of intervention.

**Participants/Inclusion and exclusion criteria**

Participants in this plan are multiparous pregnant women (second to fifth pregnancies) who are candidates for natural delivery (NVD) and meet the necessary conditions for spinal analgesia (including 4 cm cervical dilation).

**Intervention groups**

Control group: Patients receive a single spinal analgesia with an intrathecal injection of 10 micrograms of sufentanil (Abureyhan company) using a Quincke 26-gauge needle from Dr. G. Intervention group: Patients receive a single spinal analgesia with 10 micrograms of sufentanil produced by the Abureyhan company. The 26-gauge Quincke needle used is produced by the Dr.J company. Additionally, receive 8 mg of dexamethasone produced by the Abureyhan company intravenously at the same time.

**Main outcome variables**

Duration of analgesia


## General information

**Reason for update**

Given that at the time of starting the plan registration in the system, the expected time to start sampling is recorded approximately and is not considered a definitive time (due to the uncertainty of the duration of the arbitration required to approve the plan), therefore, after the arbitration is completed and the actual sampling begins, the start and end times of the plan need to be corrected.

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20190719044276N2**
Registration date: **2025-08-07, 1404/05/16**
Registration timing: **prospective**

Last update: **2026-06-13, 1405/03/23**
Update count: **1**

**Registration date**

2025-08-07, 1404/05/16

**Registrant information**


**Name**

Niloofar Khosravi

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-07-23, 1404/05/01

**Expected recruitment end date**
2026-01-21, 1404/11/01
**Actual recruitment start date**
2025-08-11, 1404/05/20
**Actual recruitment end date**
2026-01-21, 1404/11/01
**Trial completion date**
2026-01-21, 1404/11/01

**Scientific title**
The investigation of the intravenous dexamethasone’s effect on the duration of analgesia in pregnant patients undergoing spinal analgesia with opioid (Sufentanil) for Normal Vaginal Delivery (NVD)

**Public title**
Effect of Dexamethasone in the labor analgesia
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Maternal request for labor analgesia Being multiparous (second to fifth labor) Being Term Cervical dilation is equal to 4 cm Normal coagulation state Physical status classification 1 & 2 Availability of normal Non- Stress Test (NST) of fetus
**Exclusion criteria:**
Allergy to dexamethasone Allergy to opioids Pregnant women who are addicted to opioids or illegal drugs Pregnant women with psychiatric diseases Pregnancy with history of diabetes or/and hypertension diseases Pregnant women who are contraindicated for spinal techniques due to Multiple Sclerosis (MS) or other neurological diseases Refuse of pregnant women for doing spinal technique
**Age**
From **18 years** old to **40 years** old
**Gender**
Female

**Phase**
3
**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **120**
Actual sample size reached: **120**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, a simple random sampling method is used to allocate patients to two groups: intervention (receiving dexamethasone) and control (not receiving dexamethasone). First, a list of eligible patients who meet the study inclusion criteria is prepared. Each patient is assigned an identification number (from 1 to 120). Then, using the =RAND() function in Excel software, a random number between zero and one is generated for each number. Patients are sorted in ascending order based on this random number. Next, the first 60 patients are assigned to group A (control), and the second 60 patients are assigned to group B (intervention).
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this study, only the person performing the procedure (the relevant physician) is aware of the patient grouping for the procedures, and the person who evaluates the patients and records the checklist information, such as the onset of analgesia and its duration (the relevant nurse), is unaware of the patient grouping. The design analyst (principal investigator) is also unaware of the patient grouping (which groups are Group A and which groups are Group B). Patients (participants in the trial) will be informed of the design grouping method and its practical objectives before starting the necessary procedures.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Iran University of Medical Sciences
**Street address**
Iran University of Medical Sciences, Hemmat Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
۱۴۴۹۶۱۴۵۳۵
**Approval date**
2025-05-17, 1404/02/27
**Ethics committee reference number**
IR.IUMS.REC.1404.178

## Health conditions studied

### 1

**Description of health condition studied**
Labor analgesia
**ICD-10 code**
P04.0
**ICD-10 code description**
Newborn (suspected to be) affected by maternal anesthesia and analgesia in pregnancy, labor and delivery

## Primary outcomes

### 1

**Description**
duration of analgesia
**Timepoint**
Determining the patient's pain score using a visual analog scale (VAS) before the start of the intervention, at 1 and 5 minutes after the intervention, and at 2, 3, and 4 hours after the intervention.
**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Control group: In this group, patients undergo a single spinal anesthesia with an intrathecal injection of 10 micrograms of the opioid sufentanil from Abu Raihan Company. The needle used in this intervention is a Quincke model and a 26 gauge needle from Dr. G. Company.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: In this group, patients undergo spinal anesthesia once with an intrathecal injection of 10 micrograms of the narcotic sufentanil from Abu Raihan Company. The needle used in this intervention is a Quincke model and 26 gauge from Dr. G. Company. Also, at the same time as spinal anesthesia, 8 mg of dexamethasone from Abu Raihan Company is injected intravenously into the patient.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Akbarabadi hospital
**Full name of responsible person**
Niloofar Khosravi
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## Sponsors / Funding sources

### 1

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**Grant name**
Research assistant of Iran University of Medical Sciences
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Iran University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Niloofar Khosravi
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Only part of the data, such as information related to the main outcome or the like, can be shared.
**When the data will become available and for how long**
The access period starts 6 months after results are published.
**To whom data/document is available**
The data from this project will be accessible to researchers working in academic and scientific institutions.
**Under which criteria data/document could be used**
Requirements for submitting an application: 1. University professors or students who are conducting research in a field related to the subject of the project. 2. They must commit to mentioning the name of the relevant educational and medical center when using the data. 3. The data must be used to familiarize themselves with the research method, and if it can be used in statistical calculations of the project (for example, statistical comparison of several centers), it must be done with the consent of all authors of the project.
**From where data/document is obtainable**
Akbarabadi Medical Training Center Address: Tehran, Molavi St. - Bagh Ferdows Station. Phone: 55606034 Responsible person: Dr. Niloofar Khosravi, Assistant Professor of Anesthesia, Akbarabadi Center
**What processes are involved for a request to access data/document**
Submit a valid letter from the educational and scientific center requesting access to the documents (including the name of the person responsible and his/her scientific and executive position, as well as the director of the relevant center). An explanation of the reasons for requesting access to the said documents and a commitment that the documents will not be made available to unrelated persons.
**Comments**