Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effect of Dexmedetomidine's intravenous infusion on the reduction of vaginal delivery pain in nulipar and full-term women

Protocol summary

Study aim
The aim of this study was to find a way to reduce vaginal delivery pain in Nullipar and Full-term women.

Design
Non-randomized clinical trial with control group

Settings and conduct
It will be explained to patients about how pain is assessed. Then, in the intervention group, after the onset of the active phase of labor, Dexmedetomidine will be given according to the protocol and will continue until episiotomy is performed. There is no intervention in the control group to reduce pain. Patients in both groups will be evaluated for pain intensity and sedation every 5 minutes. 15 minutes after placenta delivery, the patient and midwife of both groups will be evaluated in terms of satisfaction.

Participants/Inclusion and exclusion criteria
All pregnant women, full term, nullipara, ASA CLASS 1 & 2, who will be candidate for pain relief through intravenous medications, will be included in the study. Patients with liver failure, kidney failure, grade 2 or 3 heart block,the use of psychiatric drugs, addicts to narcotic drugs will not be included in the study.

Intervention groups
In the intervention group, after the onset of the active phase of labor, the initial dose (1 µg / kg) of intravenous Dexmedetomidine (Manufacturing of Exir Pharmaceutical Company) will be infused over a 10 minute period, and then a continuous dose of 0.2 µg / kg / hour starts and with increased pain, visual analog scale score > 3, the infusion dose will gradually increase to a maximum of 1 µg / kg . And will continue until episiotomy. There is no intervention in the control group to reduce pain.

Main outcome variables
Change in severity of labor pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161022030421N5**
Registration date: **2019-07-20, 1398/04/29**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-20, 1398/04/29**
Update count: **0**

Registration date
2019-07-20, 1398/04/29

Registrant information

Name
Marzieh Lak

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2244 9013

Email address
marziehlak@bmsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2019-08-23, 1398/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Dexmedetomidine's intravenous infusion on the reduction of vaginal delivery pain in nulipar and full-term women

Public title
The effect of Dexmedetomidine intravenous infusion on reducing the pain of normal vaginal delivery.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All nulli para pregnant women Full term Class 1 and 2 American Society of Anesthesiologist Candidate for vaginal delivery
Exclusion criteria:
Patients with liver failure renal failure grade 2 or 3 heart block history of neurological and psychiatric illness drug addicts
Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **25**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah University of Medical Sciences, Mollasadra Street, Sheikh Bahaee Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435917541
Approval date
2019-02-15, 1397/11/26
Ethics committee reference number
IR.BMSU.REC.1397.250

Health conditions studied

1

Description of health condition studied
Vaginal delivery
ICD-10 code
G89
ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Change in severity of labor pain
Timepoint
After the onset of the active phase of labor, and commencing the onset of the dexmedotomidine drug, the patient will be examined for pain intensity every 5 minutes until the placenta is removed and the episiotomy is repaired.
Method of measurement
Pain Evaluation by visual analogue scale score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: after the onset of the active phase of labor, the initial dose (1 µg / kg) of intravenous Dexmedetomidine (Manufacturing of Exir Pharmaceutical Company) will be infused over a 10 minute period, and then a continuous dose of 0.2 µg / kg / hour starts and with increased pain, visual analog scale score > 3, the infusion dose will gradually increase to a maximum of 1 µg / kg . And will continue until epistolary is performed.
Category
Treatment - Drugs

2

Description
Control group:people who will not be satisfied with delivery using analgesics will enter control group, after accepting their participation in the plan. In these patients, routine care is provided.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Baqiyatallah hospital

Full name of responsible person
Marzieh Lak

Street address
Baqiyatallah University of Medical Science, Mollasadra Street, Sheikh Bahaee Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435917541

Phone
+98 21 2244 9013

Email
marziehlak@bmsu.ac.Ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Golamhossein Alishiri

Street address
Baqiyatallah University of Medical Science, Mollasadra Street, Sheikhbahai Street,Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 8755 5250

Email
ghalishiri@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Marzieh Lak

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Baqiyatallah University of Medical Science, Mollasadra Street, Sheikhbahai Street,Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435917541

Phone
+98 21 2244 9013

Email
marziehlak@bmsu.ac.Ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Marzieh Lak

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Baqiyatallah University of Medical Science, Mollasadra Street, Sheikh Bahaee Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 2244 9013

Email
marziehlak@bmsu.ac.Ir

Person responsible for updating data

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Marzieh Lak

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology
Street address
Baqiyatallah University of Medical Science, Mollasadra Street, Sheikhbahai Street,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 2244 9013
Email
marziehlak@bmsu.ac.Ir

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
All data can be shared after unidentifing people.
When the data will become available and for how long
Start the access period one month after the results are published
To whom data/document is available
People working in academic institute
Under which criteria data/document could be used
For meta-analysis
From where data/document is obtainable
by Email
What processes are involved for a request to access data/document
By sending a request to the University Vice-Chancellor for Research and obtaining a license
Comments