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Comparison between injection of local analgesia and performing a specific nerve block in the management of vaginal pain after delivery

Submission date
23/09/2020

Recruitment status
No longer recruiting

Registration date
24/01/2021

Overall study status
Completed

Last Edited
04/02/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Episiotomy or tearing of perineal tissues during childbirth is associated with significant pain in the postpartum period. Although the use of episiotomy is often debated, it remains the most common surgical procedure experienced by women. Pain from episiotomy is poorly treated, though it may be severe and can result in significant discomfort and interference with basic daily activities and adversely impact motherhood experiences.
Furthermore, episiotomy may increase the risk of chronic perineal pain, which is estimated to occur in 13% to 23% of women after episiotomy. Before the widespread use of epidural anesthesia in obstetrics, pudendal nerve block (block of the nerve supply of the perineum) was a commonly used anesthetic technique for vaginal birth reported as early as 1908. Pudendal nerve block became popular in the mid-1950s and was often used as anesthesia for childbirth into the mid-1980s. As epidural use grew in popularity, pudendal nerve block declined in the United States.
The aim of this study is to assess the effect of pudendal nerve block on pain relief after episiotomy compared to local injection of anesthesia.

Who can participate?
Women giving birth at Ain Shams University maternal Hospital in Cairo, Egypt

What does the study involve?
Women are randomly allocated to receive either pudendal nerve block or local injection of anesthesia and then the two groups are compared in terms of pain after episiotomy for the first 6 hours after delivery.

What are the possible benefits and risks of participating?
A possible benefit is to show the useful effect of pudendal nerve block in the management of post episiotomy pain relief. Possible complications are the known complications of pudendal nerve block such as injury of blood vessels or nerves.

Where is the study run from?
Ain Shams University Maternal Hospital (Egypt)

When is the study starting and how long is it expected to run for?
July 2018 to February 2019

Who is funding the study?
Ain Shams University Hospital (Egypt)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
20092018

Study information

Scientific Title
Effect of pudendal nerve block versus perineal local infiltration of analgesia in post episiotomy pain relief

Study objectives
In women in labor and undergoing episiotomy pudendal nerve block may be similar to local infiltration by analgesic as regard post episiotomy pain relief.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 20/09/2018, board of the department of obstetrics and gynecology, Ain Shams University (Ramsis St., Abbaseya, 11517 Cairo, Egypt; +20 (0)2 24346347; medicom@med.asu.edu.eg), ref: not provided

Primary study design
Interventional

Study design
Single-center interventional randomized controlled clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post episiotomy pain after delivery

Interventions
Random allocation sequence generation: a computer-generated list via MedCalc software version 13.2.2 is used, assigning each patient to a study group.

Pudendal nerve block is performed when the cervix is fully dilated with vertex station +1 to +2 using 5 ml Bupivacaine hydrochloride 0.25% (Marcaine®; 0.25%, 5 ml) plus 0.5ml dexamethasone dihydrogen phosphate 8 mg (Fortecortin® 8 mg, 0.5 ml).

The other group of patients undergo local perineal infiltration of analgesia for post episiotomy pain relief.

Follow up of pain score is performed up to 6 hours postpartum.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain measured using the Visual Analogue Scale assessed every hour for the first 6 hours postpartum starting from the time of the analgesia injection

Key secondary outcome(s)
1. Need for analgesics assessed by asking the patient every hour for the first 6 hours postpartum starting from the time of the analgesia injection
2. Delivery time (minutes) after injection of analgesia, documented at the time of delivery
3. Pregnancy outcome assessed using Apgar score at 1 and 5 min after delivery

Completion date
21/02/2019

Eligibility

Key inclusion criteria

1. Primigravida
2. Singleton term pregnancy
3. Age (20-35 years)
4. Free of medical disorders

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
100

Key exclusion criteria
1. Presence of infection
2. Coagulation abnormalities
3. History of sensitivity to local anesthetics
4. Malpresentation or malposition
5. Previous vaginal operations and or presence of any obstetric complications

Date of first enrolment
20/09/2018

Date of final enrolment
20/02/2019

Locations

Countries of recruitment
Egypt

Study participating centre
Ain Shams University
Faculty of Medicine
Ramsis St., Abbaseya
Cairo
Egypt
11517

Sponsor information

Organisation
Ain Shams University

ROR
https://ror.org/00cb9w016

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ain Shams University Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Abdelrahman Abouelhassan (Bodym93@yahoo.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			04/02/2021	No	No