

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 | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 24/01/2021 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 04/02/2021 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?
Abdelrahman Abouelhassan
bodym93@yahoo.com

Contact information

Type(s)
Public

Contact name
Mr Abdelrahman Abouelhassan

Contact details
Hindenburgstrasse 15
Hagen
Germany
58095
+49 (0)1632042180
bodym93@yahoo.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design

Single-center interventional randomized controlled clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

21/07/2018

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

Age group

Adult

Sex

Female

Target number of participants

100

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

Sponsor details

Faculty of Medicine

Ramsis St., Abbaseya

Cairo

Egypt

11517

+20 (0)2 24346347

medicom@med.asu.edu.eg

Sponsor type

University/education

Website

<http://www.asu.edu.eg/>

ROR

<https://ror.org/00cb9w016>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Ain Shams University Hospital

Results and Publications

Publication and dissemination plan

Planned publication in a high impact peer-reviewed journal

Intention to publish date

01/01/2021

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 |