Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

EFFICACY OF PARENTERAL ACETAMINOPHEN AS INTRAPARTUM ANALGESIC

Protocol summary

Study aim
Therapeutic efficacy of parenteral acetaminophen in relief of labour pain among primigravida. Attempt to create an impact to make its use more prevalent in our country.

Design
Placebo, double blinded, randomized controlled trial, phase 3, Done by principal investigator using computer generated code,130 participants 65 in each group, group A placebo and group B paracetamol, duration from may to October, 6 months duration.

Settings and conduct
Will be conducted at pharmacology department of Public sector Medical College, National University of Medical Sciences in collaboration with gynecology department Public sector Hospital Rawalpindi Pakistan. Prticipants, outcome assessor, health care provider will be blinded. Principal investigator is not blinded.by computer generated codes.

Participants/Inclusion and exclusion criteria
Inclusion criteria will be a primigravida of 18–35 year, full-term with uncomplicated spontaneous onset of labour at term (37–42 weeks gestation); singleton pregnancy; cervical dilatation of 3-5 cm and cephalic presentation of fetus. Exclusion criteria for this research will be malpresentation of fetus; multiparous women; previously scarred uterus; preterm labour; antepartum hemorrhage; history of drug allergy or hypersensitivity; fetal distress (abnormal foetal monitoring during labour); intrauterine foetal death; refusal by parturient; history of alcohol/drug abuse; systemic and local sepsis; deranged coagulation profile; obstetric complications (e.g., premature rupture of amniotic membranes) and women with clinical evidence of cephalopelvic disproportion.

Intervention groups
Group A will serve as control and will receive 100 ml I/V normal saline as placebo whereas group B will receive I/V paracetamol 1000mg in 100ml normal saline at the start of active stage of labour.

Main outcome variables
Pain assessment will be done by VAS scale.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220308054220N1**
Registration date: **2022-04-04, 1401/01/15**
Registration timing: **prospective**

Last update: **2022-04-04, 1401/01/15**
Update count: **0**
Registration date
2022-04-04, 1401/01/15

Registrant information
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Wajeha Najeeb
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National University of Medical Sciences Pakistan
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-15, 1401/02/25
Expected recruitment end date
2022-10-30, 1401/08/08
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EFFICACY OF PARENTERAL ACETAMINOPHEN AS INTRAPARTUM ANALGESIC

Public title

USE OF PARACETAMOL AS LABOUR ANALGESIC

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primigravida of 18–35 year. Full-term with uncomplicated spontaneous onset of labour at term (37–42 weeks gestation). Singleton pregnancy. Cervical dilatation of 3-5 cm. Cephalic presentation of fetus.

Exclusion criteria:

Malpresentation of fetus. Multiparous women. Previously scarred uterus (post myomectomy, post cesarean). Preterm labour. Antepartum hemorrhage. History of drug allergy or hypersensitivity. Fetal distress (abnormal foetal monitoring during labour). Intrauterine foetal death. Refusal by parturient. History of alcohol/drug abuse. Systemic and local sepsis. Deranged coagulation profile. Obstetric complications (e.g., premature rupture of amniotic membranes). Women with clinical evidence of cephalopelvic disproportion.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by simple randomization. Unit of randomization will be individuals. Tool that will be used in randomization will be computer generated codes. The random sequence of these codes will be built by computer software. The allocation concealment will also be done.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, Health care provider, Person doing intervention, Data collector, Outcome assessor all will be blind. principle investigator, Manuscript writer, Data safety and monitoring board will not be blind. Vial of placebo and paracetamol both will have computer generated code, which will only be decoded by principal investigator.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical review committee of Public sector Medical college

Street address

Abid Majeed Road Rawalpindi Cantt

City

Rawalpindi

Postal code

46000

Approval date

2022-03-17, 1400/12/26

Ethics committee reference number

ERC / ID /196

Health conditions studied

1

Description of health condition studied

Labour pain

ICD-10 code

080.0

ICD-10 code description

Delivery

Primary outcomes

1

Description

Pain assessment

Timepoint

After first dose of paracetamol in Group A and placebo in Group B administration pain will be measured at 15 minutes, 30 minutes, and then at hourly intervals till 4 hours and then readminister the second dose of paracetamol and placebo and then will measure outcome at 15 minutes, 30 minutes, and then at hourly intervals till 4 hours.

Method of measurement

Visual Analogue Scale to measure pain

2

Description

Body mass index

Timepoint

At the start of intervention

Method of measurement
Weight by weighing machine in kgs and height in feet by scale

3

Description
Pulse rate
Timepoint
Before intervention and one time in middle of 4 hours after intervention of first dose and second dose
Method of measurement
Heart rate monitor (HRM)

4

Description
Blood pressure
Timepoint
Before intervention and one time in middle of 4 hours after intervention of first dose and second dose
Method of measurement
Sphygmomonometer

Secondary outcomes

1

Description
Duration of labour
Timepoint
Duration of first stage of labour, duration of second stage, total duration of labour
Method of measurement
Clock to measure time of first and second stage of labour and total duration of labour.

2

Description
Complications during delivery
Timepoint
During three stages of labour
Method of measurement
Health care provider will measure using clinical findings

3

Description
Side-effects after intervention: Nausea, vomiting, sedation, dizziness
Timepoint
During three stages of labour
Method of measurement
Health care provider will measure using clinical findings

4

Description
APGAR
Timepoint
At 1 min and 5 min
Method of measurement
APGAR scale

Intervention groups

1

Description
Control group:In this group placebo, normal saline will be given intravenous to pregnant lady in active labour stage with 3-4 cm cervical dilation and main primary outcomes that is pain is measured at 15 min, 30 min, 1 hour, 2,3,4 hour will be measured. Other primary outcomes are BMI measured by calculating weight by weight machine, pulse meaured by HRM and blood pressure measured by sphygmomanometer before and after giving the dose. Repeat the dose after 4 hour. And again measure the pain , pulse and blood pressure following same pattren of time as for first dose. Pain will measured by VAS (visual.anslogue scale). Normal saline is 0.9% NaCl. It is 0.9grams of NaCl in 100 ml of water.Dose is 100 ml of normal saline. Secondary outcomes that are duration of labour, Apgar score measured by Apgar scale, complications during delivery will be assessed by person measuring outcomes, side effects after giving dose will be measured by outcome assessor.
Category
Placebo

2

Description
Intervention group: In this group, acetaminophen be given intravenous to pregnant lady in active labour stage with 3-4 cm cervical dilation and main primary outcomes that is pain is measured at 15 min, 30 min, 1 hour, 2,3,4 hour will be measured. Other primary outcomes are BMI measured by calculating weight by weight machine, pulse meaured by HRM and blood pressure measured by sphygmomanometer before and after giving the dose. Repeat the dose after 4 hour. And again measure the pain , pulse and blood pressure following same pattren of time as for first dose. Pain will measured by VAS (visual.anslogue scale). Both Doses will be same i.e; 1000 mg of acetaminophenin 100ml of normal saline. Secondary outcomes that are duration of labour, Apgar score measured by Apgar scale, complications during delivery will be assessed by person measuring outcomes, side effects after giving dose will be measured by outcome assessor.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Public sector hospital rawalpindi pakistan.
Full name of responsible person
Wajeha Najeeb
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Public sector medical college Rawalpindi Pakistan
Full name of responsible person
Mudassar noor
Street address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Public sector medical college Rawalpindi Pakistan
Proportion provided by this source
50
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
Public sector medical college Rawalpindi Pakistan
Full name of responsible person
Wajeha najeeb
Position
student
Latest degree
A Level or less
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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

title: Results. Tables and graphs of primary outcome and secondary outcome will be shared.

When the data will become available and for how long

it will be given in the duration of 10 months to 36 months after publishing. It will be available lifelong

To whom data/document is available

everyone

Under which criteria data/document could be used

everyone who want to take advantage of this trial results will be allowed for the service of humanity.

From where data/document is obtainable

they can talk to principal investigator of this trial Wajeha Najeeb. E-mail: wajeha.najeeb@hotmail.com

What processes are involved for a request to access data/document

email

Comments