Clinical trial results:
High versus low-dose dexamethasone for postoperative anagesia after caesarean section: a randomised, double-blind, two-center study.

Summary

EudraCT number	2020-005681-33
Trial protocol	BE
Global end of trial date	31 December 2022

Results information

Result version number	v1 (current)
This version publication date	22 May 2024
First version publication date	22 May 2024

Trial information

Trial identification

Sponsor protocol code	MVDVER102020

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Hospitals Leuven, Department of Anesthesiology
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Department of Anesthesiology, University Hospitals Leuven, +32 16344270, marc.vandevelde@uzleuven.be
Scientific contact	Department of Anesthesiology, University Hospitals Leuven, +32 16344270, marc.vandevelde@uzleuven.be

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 April 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 December 2022
Global end of trial reached?	Yes
Global end of trial date	31 December 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this trial is that the addition of high-dose dexamethasone 25 mg twice (at day 0 and day 1 after surgery) to multimodal analgesia (paracetamol and NSAIDs combined with a single-shot local anesthetic wound infiltration) will result in more effective analgesia and better patient functionality the first 48 hours following Caesarean section compared with a standard 5-mg dose.

Protection of trial subjects:

Yes

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 February 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 210
Worldwide total number of subjects	210
EEA total number of subjects	210

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	210
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

If eligible, a convenience sample of patients (when the investigators were available) were approached the day of cesarean section prior to surgery and given verbal and written information.

Pre-assignment

Screening details:

Inclusion criteria: elective CS scheduled with neuraxial anesthesia, > 36 weeks of gestation, and ASA physical status II.
Exclusion criteria: labor, ASA physical status III and IV, known allergies to the study drugs, diabetes, chronic use of corticosteroids or opioids, antepartum administration of corticosteroids, peptic ulcers, <18yrs of age

Period 1

Period 1 title	Study period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Random allocation was performed using a computer-generated permuted block randomization list stratified on study site (variable block-size with 1:1 allocation). Allocation concealment was achieved using sequentially numbered opaque sealed envelopes containing group assignments. An anesthetist or midwife not involved in patient management or data collection opened the envelope before surgery and prepared the study medication

Arms

Are arms mutually exclusive?	Yes
Arm title	High-dose dexamethasone

Arm description:

2 x 25 mg of dexamethasone

Arm type	Active comparator
Investigational medicinal product name	dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intravenous bolus use

Dosage and administration details:

25 mg dexamethasone in 100 ml saline bag

Arm title	Low-dose dexamethasone

Arm description:

1 x 5mg of dexamethasone

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	High-dose dexamethasone	Low-dose dexamethasone
Started	105	105
Completed	105	105

Baseline characteristics

End points

End points reporting groups	
Reporting group title	High-dose dexamethasone
Reporting group description: 2 x 25 mg of dexamethasone	
Reporting group title	Low-dose dexamethasone
Reporting group description: 1 x 5mg of dexamethasone	

Primary: primary outcome	
End point title	primary outcome
End point description: the cumulative pain score with movement from 4 to 48 hours after CS assessed with area under the NRS score x time curve (AUC	
End point type	Primary
End point timeframe: from 4 to 48 hours after CS	

End point values	High-dose dexamethasone	Low-dose dexamethasone		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	105		
Units: cumulative pain score for movement				
number (confidence interval 95%)	2.6 (2.4 to 3.4)	3.1 (2.9 to 3.9)		

Statistical analyses

Statistical analysis title	Statistical analysis
Comparison groups	High-dose dexamethasone v Low-dose dexamethasone
Number of subjects included in analysis	210
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: untill 8 weeks after Cesarean section	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups	
Reporting group title	High-dose dexamethasone
Reporting group description: -	
Reporting group title	Low-dose dexamethasone
Reporting group description: -	

Serious adverse events	High-dose dexamethasone	Low-dose dexamethasone	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 105 (1.90%)	2 / 105 (1.90%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Surgical and medical procedures			
Haemorrhage	Additional description: Surgical revision for abdominal bleeding		
subjects affected / exposed	2 / 105 (1.90%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	High-dose dexamethasone	Low-dose dexamethasone	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 105 (61.90%)	68 / 105 (64.76%)	
Pregnancy, puerperium and perinatal conditions			
nipple cracks			
subjects affected / exposed	15 / 105 (14.29%)	26 / 105 (24.76%)	
occurrences (all)	16	26	
Blood and lymphatic system disorders			

anemia subjects affected / exposed occurrences (all)	13 / 105 (12.38%) 13	8 / 105 (7.62%) 8	
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all)	58 / 105 (55.24%) 58	51 / 105 (48.57%) 51	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported