Clinical trial results:
High dose steroids in liver resection – effects on complications and endothelial function in the immediate postoperative phase. A randomized, double-blind, controlled trial

Summary

EudraCT number	2017-002652-81
Trial protocol	DK
Global end of trial date	28 September 2020

Results information

Result version number	v1 (current)
This version publication date	21 May 2022
First version publication date	21 May 2022
Summary attachment (see zip file)	article (lever.pdf)

Trial information

Trial identification

Sponsor protocol code	DEXLEV01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03403517
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, 2200, Denmark,
Public contact	Kristin Julia Steinthorsdottir, Rigshospitalet, 0045 35451003,
Scientific contact	Kristin Julia Steinthorsdottir, Rigshospitalet, 0045 35451003,

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	28 September 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 August 2020
Global end of trial reached?	Yes
Global end of trial date	28 September 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effects of high dose steroids on complications after liver resection

Protection of trial subjects:

all procedures were standard protocol

Background therapy:

standard procedure, eras described elsewhere

Evidence for comparator: -

Actual start date of recruitment	04 September 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 174
Worldwide total number of subjects	174
EEA total number of subjects	174

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)	50
From 65 to 84 years	94
85 years and over	30

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All patients scheduled for open liver surgery without biliary reconstruction were consecutively screened for inclusion. Patients considered were 18 years of age or older, and able to provide informed oral and written consent. Exclusion criteria were: planned simultaneous operation on other organs, simultaneous operation for hernia with inserti

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Data analyst, Carer, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	high dose glucocorticoid

Arm description:

10 mg/kg methylprednisolone

Arm type	Experimental
Investigational medicinal product name	methylprednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Intravenous drip use

Dosage and administration details:

The high-dose (HD) group received 10 mg/kg methylprednisolone (Solu-medrolVR , Pfizer, Ballerup, Denmark)

Arm title	standard dose glucocorticoid

Arm description:

8 mg dexamethasone

Arm type	Active comparator
Investigational medicinal product name	dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Intravenous drip use

Dosage and administration details:

the standard-dose (SD) group received 8mg dexamethasone (Dexavit; Vital Pharma Nordic, Denmark).

Number of subjects in period 1	high dose glucocorticoid	standard dose glucocorticoid
Started	88	86
Completed	88	86

Baseline characteristics

Reporting groups	
Reporting group title	high dose glucocorticoid
Reporting group description:	
10 mg/kg methylprednisolone	
Reporting group title	standard dose glucocorticoid
Reporting group description:	
8 mg dexamethasone	

Reporting group values	high dose glucocorticoid	standard dose glucocorticoid	Total
Number of subjects	88	86	174
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	65.2	64.4	
standard deviation	± 11.2	± 12.0	-
Gender categorical			
Units: Subjects			
Female	27	30	57
Male	61	56	117

End points

End points reporting groups	
Reporting group title	high dose glucocorticoid
Reporting group description: 10 mg/kg methylprednisolone	
Reporting group title	standard dose glucocorticoid
Reporting group description: 8 mg dexamethasone	

Primary: primary eindpoint	
End point title	primary eindpoint
End point description: Number of patients with a complication in the post anesthesia care unit	
End point type	Primary
End point timeframe: the duration of the trial	

End point values	high dose glucocorticoid	standard dose glucocorticoid		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	86		
Units: number of patients	51	58		

Statistical analyses

Statistical analysis title	rr
Statistical analysis description: risk ratio	
Comparison groups	high dose glucocorticoid v standard dose glucocorticoid
Number of subjects included in analysis	174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.213
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.08

Variability estimate	Standard deviation

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: trial period + 30 days	
Assessment type	Systematic

Dictionary used	
Dictionary name	icd-10
Dictionary version	10

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: see the publication

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/34480563