Clinical trial results:
The effect of prostacyclin on haemostasis as evaluated by thrombelastography and endothelial markers in patients undergoing major abdominal surgery. A pilot study.

Summary

EudraCT number	2011-005234-19
Trial protocol	DK
Global end of trial date	25 January 2014

Results information

Result version number	v1 (current)
This version publication date	28 May 2022
First version publication date	28 May 2022

Trial information

Trial identification

Sponsor protocol code	ET_Abdominal

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark, DK-2100
Public contact	Pär Ingemar Johansson, MD, Rigshospitalet, Transfusion Medicines Unit, Capital Blood Bank 2034, +45 35452030, per.johansson@regionh.dk
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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	25 January 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of continues prostacyclin infusion in patient undergoing major abdominal surgery. Main endpoint is change in concentration of endothelial activation markers from baseline to discharger from postoperative ward or 24 hours postoperatively, whichever comes first.

Protection of trial subjects:

Patients included in this trial is admitted to the hospital undergoing surgery and will be closely monitored according to standard practice at all time.

Background therapy:

Standard of care

Evidence for comparator:

Isotonic water is chosen as comparator in this trial to reflect standard of care

Actual start date of recruitment	01 February 2012
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	Denmark: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	9
From 65 to 84 years	7

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients are only recriuted at Rigshospitalet undergoing abdominal surgery. Informed consent will be collected before inklusion in the trial.
patients are recruited in a period from October 2013 to February 2014

Pre-assignment

Screening details:

Patients undergoing abdominal surgery(pancreaticoduodenectomy) are subject for screening. All patients must be 18 years old or above.

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	Subject, Investigator, Data analyst

Blinding implementation details:

Patients were randomized to either prostacyclin or placebo 8saline). Both are colorless fluid and it’s not possible to distinct those from each other. The infusion is given in a blinded manner, thus either the patient or the treating physician know what the patients receive.

Arms

Are arms mutually exclusive?	Yes
Arm title	Intervention arm

Arm description:

patients in this arm receive prostacyclin (Ilomedin) infusion

Arm type	Experimental
Investigational medicinal product name	Ilomedin
Investigational medicinal product code	
Other name	Prostacyclin
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Prostacyclin infusion is given at a dose at 1 ng/kg/min from start of surgery until 6 hours postoperatively.

Arm title	Placebo arm

Arm description:

This arn is isotonic saline given as placebo

Arm type	Placebo
Investigational medicinal product name	Isotonic saline
Investigational medicinal product code	
Other name	NaCl 0.9%
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Prostacyclin infusion is given at a dose at 1 ng/kg/min from start of surgery until 6 hours postoperatively.

Number of subjects in period 1	Intervention arm	Placebo arm
Started	8	8
Completed	8	8

Baseline characteristics

Reporting groups	
Reporting group title	Intervention arm
Reporting group description: patients in this arm receive prostacyclin (Ilomedin) infusion	
Reporting group title	Placebo arm
Reporting group description: This arn is isotonic saline given as placebo	

Reporting group values	Intervention arm	Placebo arm	Total
Number of subjects	8	8	16
Age categorical Units: Subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	5	4	9
From 65-84 years	3	4	7
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	2	2	4
Male	6	6	12

End points

End points reporting groups

Reporting group title	Intervention arm
Reporting group description:	
patients in this arm receive prostacyclin (Ilomedin) infusion	
Reporting group title	Placebo arm
Reporting group description:	
This arn is isotonic saline given as placebo	

Primary: Trombomodulin

End point title	Trombomodulin
End point description:	
The data reflects the difference between the groups, indication that souble trombomodulin increased more in the placebo group than the intervention group	
End point type	Primary
End point timeframe:	
FRom start of surgery until 6 hours post surgery.	

End point values	Intervention arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	8		
Units: ng/ml				
median (inter-quartile range (Q1-Q3))				
sTM level	0.67 (0.42 to 0.91)	1.83 (1.1 to 2.36)		

Statistical analyses

Statistical analysis title	Primary endpoint
Comparison groups	Placebo arm v Intervention arm
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)

Secondary: Transfusion requirements

End point title	Transfusion requirements

End point description:

The data reflects the difference between the groups, indicating that the placebo group received more red blood cells than the intervantion group

End point type	Secondary

End point timeframe:

From start of surgery until 6 hours post surgery

End point values	Intervention arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	8		
Units: ml				
median (inter-quartile range (Q1-Q3))				
RBC transfusion	0 (0 to 0)	115 (0 to 296)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse events were reported from start of surgery to 12 hours post surgery.

Adverse event reporting additional description:

All AE and SAE will be recorded in the patients electronic hospital file, however only AR and SAR will be recorded in the patient CRF.

Assessment type	Systematic

Dictionary used

Dictionary name	None
Dictionary version	0

Reporting groups

Reporting group title	Overall trail

Reporting group description:

No AE is recorded

Serious adverse events	Overall trail		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Overall trail		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)		

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: As these pateints are severily ill, AE are not recorded as seperate AE but as part of the patients regular medical chart.

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/27926661