Clinical trial results:
Vertebroplasty versus periost infiltration with lidocain as pain treatment in osteoporotic fractures in the thoracic and lumbar spine

Summary

EudraCT number	2010-024050-10
Trial protocol	DK
Global end of trial date	18 December 2015

Results information

Result version number	v1 (current)
This version publication date	27 February 2021
First version publication date	27 February 2021

Trial information

Trial identification

Sponsor protocol code	2010001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Rygcenter Syddanmark
Sponsor organisation address	Østre Hougvej 55, Middelfart, Denmark, 5500
Public contact	Mikkel Andersen, Rygkirurgisk forskningsenhed, Rygcenter Syddanmark, 0045 63484198, mikkel@dadlnet.dk
Scientific contact	Mikkel Andersen, Rygkirurgisk forskningsenhed, Rygcenter Syddanmark, 0045 63484198, mikkel@dadlnet.dk

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	18 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 December 2015
Global end of trial reached?	Yes
Global end of trial date	18 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary purpose of the RCT was to compare the pain relieving effect and health related quality of life during a one-year follow-up period, between PVP procedure and a SHAM-procedure, in patients with acute OVCF affecting T6-L5

Protection of trial subjects:

All patients were examined with preoperative blood samples, to exclude infections, disease of the coagulation system or malignancies.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 May 2011
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: 52
Worldwide total number of subjects	52
EEA total number of subjects	52

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)	6
From 65 to 84 years	45
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Osteoporotic fractures, with a history of pain less than 8 weeks from the level T6-L5 and MRI that included a STIR with edema present at the time of inclusion. Baseline value at least 7 on a VAS score in either rest or activity

Pre-assignment

Screening details:

Osteoporotic fractures, with a history of pain less than 8 weeks from the level T6-L5 and MRI that included a STIR with edema present at the time of inclusion. Baseline value at least 7 on a VAS score in either rest or activity.

Pre-assignment period milestones

Number of subjects started	52
Number of subjects completed	52

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:

The OR-nurse opened the designated envelope with a given patients project-number after the surgeon placed the Jamshidi needles within the fractured vertebral body through the pedicles. In all cases, PMMA cement was mixed to create the odor similar to a PVP-procedure. If the subject was randomized to PVP, the PMMA cement was mixed, and 2 ml of cement were injected into the pedicle under constant fluoroscopic guidance.

Arms

Are arms mutually exclusive?	Yes
Arm title	PVP Group

Arm description:

If the subject was randomized to PVP, the PMMA cement was mixed, and 2 ml of cement were injected into the pedicle under constant fluoroscopic guidance, injection was stopped if the cement reached the posterior border of the vertebrae

Arm type	Experimental
Investigational medicinal product name	PVP cement
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Implant
Routes of administration	Intraosseous use

Dosage and administration details:

PMMA cement was mixed, and 2 ml of cement were injected into the pedicle under constant fluoroscopic guidance

Arm title	Sham

Arm description:

The SHAM procedure was a procedure where 2 ml of lidocaine (10 mg/ml) were injected into each Jamshidi needle

Arm type	Placebo

Investigational medicinal product name	lidocaine (10 mg/ml)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intraosseous use

Dosage and administration details:

2 ml of lidocaine (10 mg/ml) were injected into each Jamshidi needle

Number of subjects in period 1	PVP Group	Sham
Started	26	26
Completed	22	24
Not completed	4	2
Physician decision	4	2

Baseline characteristics

End points

End points reporting groups

Reporting group title	PVP Group
Reporting group description:	
If the subject was randomized to PVP, the PMMA cement was mixed, and 2 ml of cement were injected into the pedicle under constant fluoroscopic guidance, injection was stopped if the cement reached the posterior border of the vertebrae	
Reporting group title	Sham
Reporting group description:	
The SHAM procedure was a procedure where 2 ml of lidocaine (10 mg/ml) were injected into each Jamshidi needle	
Subject analysis set title	VAS
Subject analysis set type	Per protocol
Subject analysis set description:	
Back pain VAS-score (0-100) was collected at inclusion, 6 hours postoperatively, and every week for the first 3 months.	

Primary: Pain VAS

End point title	Pain VAS
End point description:	
End point type	Primary
End point timeframe:	
Back pain VAS-score (0-100) was collected at inclusion, 6 hours postoperatively, and every week for the first 3 months	

End point values	PVP Group	Sham		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	24		
Units: 0-100				
arithmetic mean (standard error)	6.88 (± 4.35)	8.64 (± 4.55)		

Statistical analyses

Statistical analysis title	Stats
Statistical analysis description:	
The statistical analyses were conducted in SAS version 9,4 (SAS institute, Carry, NC). Unpaired student’s t-test was used to compare continuous variables.	
Comparison groups	PVP Group v Sham
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)

Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard error of the mean

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: one year post-treatment	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups	
Reporting group title	PVP group
Reporting group description: -	
Reporting group title	Sham

Reporting group description:

The SHAM procedure was a procedure where 2 ml of lidocaine (10 mg/ml) were injected into each Jamshidi needle

Serious adverse events	PVP group	Sham	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	PVP group	Sham	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (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: Very small sample size – lidocaine is a well-tolerated drug

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