Clinical trial results:
Postoperative treatment with parathyroidea hormone Forteo® in patients undergoing posterolateral spinal fusion surgery. A prospektive and a randomized double-blinded, placebo-controlled study

Summary

EudraCT number	2011-006152-36
Trial protocol	DK
Global end of trial date	13 June 2018

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	1774

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00615236
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rygcenter Syddanmark
Sponsor organisation address	Oestre Hougvej 55, Middelfart, Denmark, 5500
Public contact	Mikkel Andersen, Rygkirurgisk forskningsenhed, SLB, 0045 63484198, mikkel@dadlnet.dk
Scientific contact	Mikkel Andersen, Rygkirurgisk forskningsenhed, SLB, 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	13 June 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary aim of this study is to examine the effect on
clinical outcome of postoperative treatment with Forteo® by evaluating self reported disability,(ADL functions-data) in elderly patients undergoing spinal stabilization surgery compared with placebotreatment.

Protection of trial subjects:

While the patients were hospitalized, a research nurse instructed the patients in proper injection techniques and self-administration of 20 µg teriparatide, PTH or placebo (identical pen injection devices with saline) during the three months (90 days) postoperative period. Both patient groups received supplemental calcium and vitamin D supplements and were monitored during the treatment period for any complications or side effects by the operating surgeon. Additional control blood samples, at discharge (4-5 days postoperatively) and at follow-ups were monitored by a spine surgeon at the department, David Krum Møller (DKM) and an endocrinologist at Odense University Hospital, Pernille Hermann (PH). Serum calcium, in particular, was closely monitored, because of the risk of hypercalcemia after teriparatide treatment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2012
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: 101
Worldwide total number of subjects	101
EEA total number of subjects	101

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)	7
From 65 to 84 years	91
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

The referral criteria for the unit comprise leg pain, an episode of walking limitation with a duration of three to 12 months and insufficient effect of conservative treatment

Pre-assignment

Screening details:

Eligible patients were identified through consecutive screening of clinic schedules of ambulatory visits.

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, Data analyst, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

pen injection devices with saline

Arm type	Placebo
Investigational medicinal product name	Saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Percutaneous use

Dosage and administration details:

1 ml

Arm title	Intervention

Arm description:

recombinant human parathyroid hormone [PTH] [1-34]

Arm type	Experimental
Investigational medicinal product name	recombinant human parathyroid hormone [PTH] [1-34]
Investigational medicinal product code	
Other name	Forteo®
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

20 µg teriparatide, PTH

Number of subjects in period 1	Placebo	Intervention
Started	51	50
Completed	46	41
Not completed	5	9
Physician decision	5	9

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description: pen injection devices with saline	
Reporting group title	Intervention
Reporting group description: recombinant human parathyroid hormone [PTH] [1-34]	

Reporting group values	Placebo	Intervention	Total
Number of subjects	51	50	101
Age categorical Units: Subjects			

Age continuous			
mean age 71 years (SD 1,01)			
Units: years			
arithmetic mean	70	71	
standard deviation	± 0.88	± 1.01	-
Gender categorical Units: Subjects			
Female	44	39	83
Male	7	11	18

End points

End points reporting groups	
Reporting group title	Placebo
Reporting group description: pen injection devices with saline	
Reporting group title	Intervention
Reporting group description: recombinant human parathyroid hormone [PTH] [1-34]	

Primary: 12 months post-operatively, compared to placebo	
End point title	12 months post-operatively, compared to placebo
End point description:	
End point type	Primary
End point timeframe: One year post operative	

End point values	Placebo	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	41		
Units: ODI				
arithmetic mean (standard deviation)	39.24 (± 12.59)	36.24 (± 12.61)		

Statistical analyses

Statistical analysis title	Stats
Statistical analysis description: Descriptive statistics, including mean (standard deviation (SD)) or median (interquartile range (IQR)), for continuous variables. All analyses were conducted with STATA 15 (StataCorp, 2000, College Station, TX: Stata Corporation, USA).	
Comparison groups	Placebo v Intervention
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	non-inferiority
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 postoperative

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	PTH Group
Reporting group description: -	
Reporting group title	Placebo Group
Reporting group description: -	

Serious adverse events	PTH Group	Placebo Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 51 (0.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	PTH Group	Placebo Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 51 (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 with only 41 patients completing the trail in the intervention group

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