Does systemic administration of parathyroid hormone after non-instrumented spinal fusion surgery improve fusion rates and fusion mass in elderly patients compared to placebo in patients with degenerative lumbar spondylolisthesis?

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Background

Few studies have investigated the effects of parathyroid hormone (PTH) therapy on fusion in patients undergoing spinal arthrodesis.

Early studies showed a more robust fusion mass with PTH after spinal fusion surgery.

But the efficiency of PTH on non-instrumented posterolateral spinal fusion surgery remains unclear.

Parathyroid hormone therapy

Teripartide: A potential solution?

Could PTH have a positive impact on outcomes of non-instrumented arthrodesis

?

Study design

A prospective, randomized, double-blind and placebo-controlled clinical trial

Comparing PTH to placebo (saline)

A single center study conducted in accordance with the CONSORT guidelines.

Intervention

The patients injected themselves once a day in 3 months.

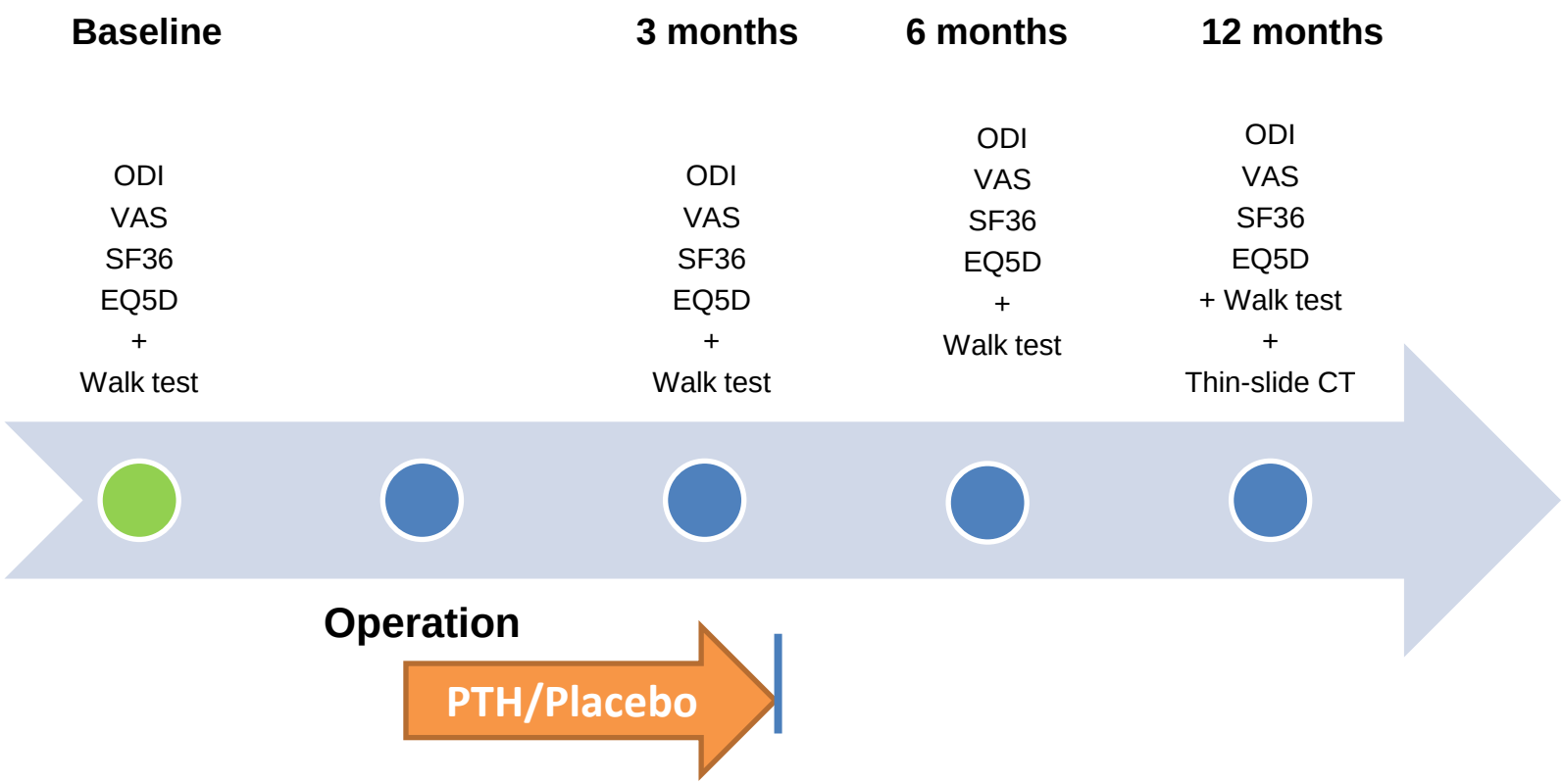
20 µg Teriparatide
or
Placebo (identical pen injection devices with saline).

On the day before surgery the patients were instructed by a research nurse in proper injection techniques.

Timeline and datacollection

The patients were randomized, by a pharmacist, in blocks of 10 to spinal decompression and posterolateral fusion surgery, with or without subsequent treatment with PTH in a 1:1 fashion.

Enrolment, surgery and follow-up were completed between May 2013 and April 2017.



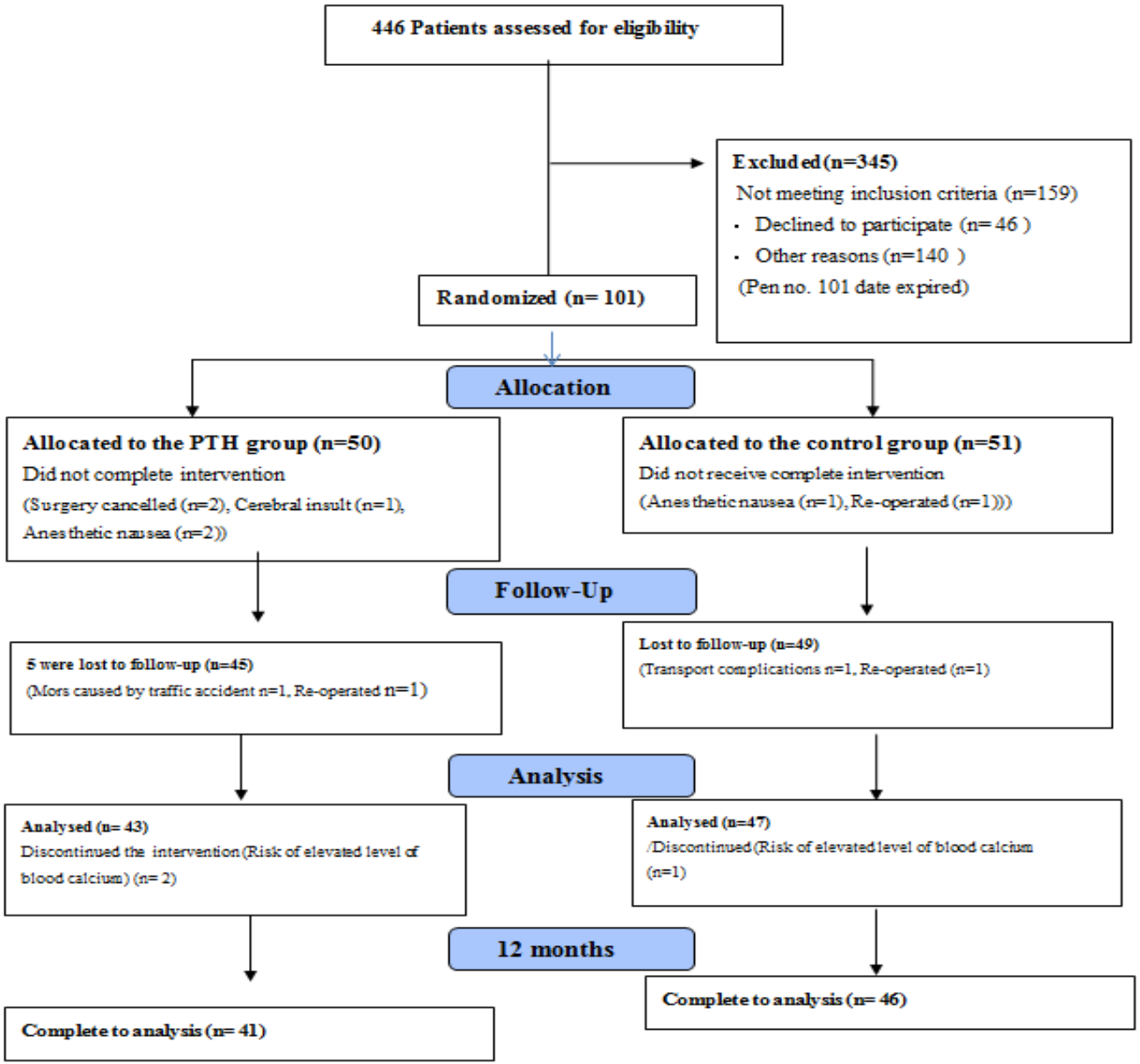
Assesment of fusion

The fusion status was evaluated from the CT scans performed at 12 months follow up.

- **Fusion quality: Area** 

Houndsfield, HU
- **Fusion volume** 
- **Fusion classification: “A reversed Glassmann”**

Figure 1 CONSORT Flow diagram showing the flow of participants through each stage of the study



Study population

Overall patients characteristics			
	PTH	**Placebo**	**P-value**
No of patients	41	46	0.582
Male, N (%)	11 (27)	7 (15)	0.182
Age, Mean (SD)	71 (1.01)	70 (0.88)	0.452
Body Mass Index, kg/m^2, Mean (SD)	27.48 (4.18)	26.56 (3.06)	0.242
Former Smokers, N (%)	1 (2.3%)	2 (4.3%)	1.000

Fusion - quality and volume

Fusion materials quality and volume	PTH group	Control group	P-value
No. of patients	41	46	0.582
Total number of surgical levels, N	47	52	0.832
One level	35 (85)	40(87)	0.830
Two levels	6 (15)	6 (13)	1.000
Fusion mass (areal x HU) per level, mm^2, Mean (SD)	16350.3(10836.10)	17538.9 (15980.18)	0.689
Mean volume of the fusion materials per level, mm^3, Mean (SD)	44.89 (30.96)	43.07 (28.89)	0.777

Fusion - classification

Fusion rates grading			P-value = 0.165
Grade	PTH group	Control group	Fused:? Yes or No
1 Solid bilateral fusion, N (%)	2 (4.9)	10 (21.7)	Yes
2 Solid unilateral fusion, N (%)	10 (24.4)	7 (15.2)	Yes
3 Partial bilateral fusion, N (%)	11 (26.1)	8 (17.4)	No
4 Partial unilateral fusion, N (%)	9 (22)	12 (26.1)	No
5 No fusion N (%)	9 (22)	9 (19.6)	No

Conclusions

PTH treatment was well tolerated but did not provide additional benefits regarding clinical outcome or in achieving a solid fusion after surgical arthrodesis, compared with placebo at 12 months.

Disclosures:
This study was supported financially by the Department of Orthopaedic Surgery, Vejle, Lillebaelt Hospital, The Region of Southern Denmark and Eli Lilly