Efficacy and safety of Etelcalcetide in patients receiving Hemodialysis with Secondary Hyperparathyroidism: Real life data

1. Griveas,

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Private Dialysis Unit “Nefroiatrikí”, Athens, Greece
Treatment of secondary hyperparathyroidism: the clinical utility of etelcalcetide

Under normal physiological conditions (Figure 1), the principal regulator of PTH secretion and parathyroid gland function is the calcium-sensing receptor (CaSR). Activation of the CaSR by serum calcium rapidly inhibits PTH synthesis and secretion and parathyroid gland growth. Furthermore, the CaSR influences PTH gene expression and may also upregulate the vitamin D receptor (VDR).
Secondary hyperparathyroidism (sHPT)

Attempt to control the disturbed calcium, phosphorus, and vitamin D metabolism. sHPT causes vascular and soft-tissue calcification and leads to disturbances of mineral metabolism. CKD-related mineral and bone disorder (CKD-MBD).

CKD-MBD abnormalities have also been implicated as risk factors for the very rare but devastating calcific and thrombotic arteriolopathy calciphylaxis and lead to reduced health-related quality of life (HR QoL).

The indication for sHPT treatment results from these clinical consequences.

sHPT-associated high FGF23 is independently associated with left ventricular hypertrophy, cardiovascular events and premature death.
Abnormalities in Metabolic Parameters Are Consequences of SHPT: Management of PTH, Ca, and P

Treatment approaches to the management of SHPT include Ca x P, PTH, and vitamin D.

Use of vitamin D and phosphate binders alone provide no direct way to control PTH levels without the risk of raising Ca and P levels.

Ca = calcium; P = phosphate; PTH = parathyroid hormone; SHPT = secondary hyperparathyroidism.
<table>
<thead>
<tr>
<th></th>
<th><strong>Cinacalcet</strong></th>
<th><strong>Etelcalcetide</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class</strong></td>
<td>First-generation</td>
<td>Second-generation</td>
</tr>
<tr>
<td></td>
<td>calcimimetic type II</td>
<td>calcimimetic type II</td>
</tr>
<tr>
<td></td>
<td>Small organic molecule</td>
<td>Octapeptide</td>
</tr>
<tr>
<td><strong>Molecular formula</strong></td>
<td>( C_{22}H_{23}F_{3}N )</td>
<td>( C_{38}H_{73}N_{21}O_{10}S_{2} )</td>
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<tr>
<td><strong>Molecular weight</strong></td>
<td>394 Da</td>
<td>1,048 Da</td>
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<tr>
<td><strong>Mode of action at</strong></td>
<td>Allosteric modulator</td>
<td>Allosteric modulator and direct agonist</td>
</tr>
<tr>
<td>CaSR</td>
<td>Transmembrane domain</td>
<td>Extracellular domain</td>
</tr>
<tr>
<td><strong>Mode of</strong></td>
<td>Daily oral</td>
<td>Thrice-weekly intravenously at the</td>
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<tr>
<td>interaction with CaSR</td>
<td></td>
<td>end of hemodialysis session</td>
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<tr>
<td><strong>Mode of</strong></td>
<td></td>
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<tr>
<td>administration</td>
<td></td>
<td><strong>Abbreviation</strong>: CaSR, calcium-sensing receptor.</td>
</tr>
</tbody>
</table>
On-going biochemical profile

Controls

- a) Diabetics
- b) Over 65 years old
- γ) naïve, monotherapy, replacement
- δ) PTH<500 pg/ml or 500 pg/ml<PTH<700 pg/ml or PTH>700 pg/ml

Protocol Etelcalcetide

Estimation Heart function

Start with 41 gradually to 60 pts

Ca, Hct, Hb, PTH, Ca

Target PTH: 200-350 pg/ml

End of study

2018
**Management Ca**

- \(7.5 \text{ mg/dl} < \text{Ca} < 8.3 \text{ mg/dl} \) with no symptoms:
  - Dose arrangement or other maneuvers
- \(< 7.5 \text{ mg/dl} \): cessation of therapy

**Target PTH:**

200-350 pg/ml
Interesting cases

Calciphylaxis and Tumoral Calcinosis
**PTH behaviour**

**PTH** before starting i.v. Etelcalcetide was \(823\) pg/mils.

**PTH** after one month therapy with i.v. Etelcalcetide was \(654.8\) pg/mils \((p<0.05)\).
Ca before starting therapy was 8.68 mg/dl.

Ph levels were also significantly reduced from 7.28 to 5.04 mg/dl (p<0.05).

Name Here

5 pts < 7.5 mg/dl
3 in normal values in a month
1 change of dose
1 tempor. cessation

Ca a week after was 8.61 mg/dl (p=NS).
<table>
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<tr>
<th>Study</th>
<th>Study design</th>
<th>Country/region</th>
<th>Study population (n)</th>
<th>Study duration</th>
<th>Comparator</th>
<th>Etcalcalcetide intervention</th>
<th>Changes in iPTH: results of etcalcalcetide vs comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Martin et al&lt;sup&gt;44&lt;/sup&gt;</td>
<td>Double-blind, randomized placebo-controlled, multicenter</td>
<td>USA</td>
<td>28 (total)</td>
<td>28 days</td>
<td>Placebo</td>
<td>Single dose of study drug Cohorts 1-3: two-period crossover design with 7–14 days interdose interval: cohort 1: 1.5 mg; cohort 2: 10 mg; cohort 3: 20 mg Cohorts 4 and 5: 1:1 randomization; cohort 4: 40 mg; cohort 5: 60 mg</td>
<td>Mean change from baseline at discharge (-3 days after application): cohort 3: -48.5%; cohort 4: -49.3%; cohort 5: -62.6%</td>
</tr>
<tr>
<td>Bell et al&lt;sup&gt;42&lt;/sup&gt;</td>
<td>Double-blind, randomized placebo-controlled, multicenter</td>
<td>USA</td>
<td>78</td>
<td>2 weeks</td>
<td>Placebo</td>
<td>Cohort 1: 5 mg thrice weekly Cohort 2: 10 mg thrice weekly Cohort 3: 5 mg thrice weekly</td>
<td>Mean change from baseline to efficacy period: cohort 2: -49.4% (P&lt;0.05); cohort 3: -33.0% (P&lt;0.05)</td>
</tr>
<tr>
<td>Block et al&lt;sup&gt;44&lt;/sup&gt;</td>
<td>Two parallel, multicenter, randomized, double-blind, placebo-controlled trials</td>
<td>USA, Canada, Europe, Israel, Russia, Australia</td>
<td>1,023 (trial A 508, trial B 515)</td>
<td>26 weeks</td>
<td>Placebo</td>
<td>Starting dose 5 mg thrice weekly; titration in increments of 2.5 or 5 mg at weeks 5, 9, 13, 17; maximum dose 15 mg thrice weekly</td>
<td>Proportion of patients achieving &gt;30% reduction: trial A, 74.0% vs 8.3% (P&lt;0.001); trial B, 75.3% vs 9.6% (P&lt;0.001)</td>
</tr>
<tr>
<td>Block et al&lt;sup&gt;43&lt;/sup&gt;</td>
<td>Randomized, double-blind, double-dummy active clinical trial</td>
<td>USA, Canada, Europe, Russia, New Zealand</td>
<td>683</td>
<td>26 weeks</td>
<td>Cinacalcet</td>
<td>Starting dose 5 mg thrice weekly; titration in increments of 2.5 or 5 mg at weeks 5, 9, 13, 17; maximum dose 15 mg Starting dose of oral cinacalcet 30 mg daily, titration in increments of 30 mg at weeks 5, 9, 13, 17; maximum dose 180 mg daily</td>
<td>Proportion of patients achieving &gt;30% reduction: 68.2% vs 57.7% (noninferiority, P&lt;0.001; superiority, P=0.004)</td>
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<tr>
<td>Fukagawa et al&lt;sup&gt;43&lt;/sup&gt;</td>
<td>Multicenter, randomized, double-blind, placebo-controlled, parallel-group</td>
<td>Japan</td>
<td>155</td>
<td>12 weeks</td>
<td>Placebo</td>
<td>Starting dose 5 mg thrice weekly; titration at 4-week intervals, maximum dose 15 mg thrice weekly</td>
<td>Proportion of patients achieving target range of 60-240 pg/mL: 59.0% vs 1.3% (P&lt;0.001)</td>
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</table>

Abbreviations: iPTH, intact parathyroid hormone.
AMG 416 (velcalcetide) is a novel peptide for the treatment of secondary hyperparathyroidism in a single-dose study in hemodialysis patients

Kevin J. Martin, Karen Pickthorn, Saling Huang, Geoffrey A. Block, Andrew Vick, Peter F. Mount, David A. Power and Gregory Bell

1Division of Nephrology, Saint Louis University School of Medicine, Saint Louis, Missouri, USA; 2Amgen, Inc, Thousand Oaks, California, USA; 3Denver Nephrology, Denver, Colorado, USA; 4WIR Research, Ashland, Ohio, USA; 5Austin Hospital, Melbourne.
Effect of Etelcalcetide vs Placebo on Serum Parathyroid Hormone in Patients Receiving Hemodialysis With Secondary Hyperparathyroidism

Two Randomized Clinical Trials

Geoffrey A. Block, MD; David A. Bashford, MD; John Cunningham, DN; Timia B. Druske, MD; Markus Ketteler, MD; Rashmi Kishanam, MD; Kevin J. Martin, MB; Bo C. T. Christan Mu, MD; Sharron M. Mas, MD; Utpal D. Patel, MD; Jastine Silver, MD; David M. Spiegel, MD; LuLu Sterling, PhD; Liren Vakal MD; Glenn M. Chertow, MD, MPH
Figure 2. Mean Percentage Change From Baseline by Study Week in Parathyroid Hormone, Corrected Calcium, and Phosphate concentrations by Randomized Group in Each Trial.

A. Parathyroid hormone concentrations in trial A.

B. Parathyroid hormone concentrations in trial B.

C. Corrected calcium concentrations in trial A.

D. Corrected calcium concentrations in trial B.

E. Phosphate concentrations in trial A.

F. Phosphate concentrations in trial B.

Error bars indicate 95% CIs. Week 77 was a posttreatment visit.
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<th>Adverse Events</th>
<th>No. (%) of Participants</th>
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<tr>
<td></td>
<td>Trial A</td>
<td>Trial B</td>
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<tr>
<td></td>
<td>Etelcalcetide (n = 251)</td>
<td>Placebo (n = 254)</td>
<td>Etelcalcetide (n = 252)</td>
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<td>Blood calcium decrease a</td>
<td>153 (61.0)</td>
<td>21 (8.3)</td>
<td>168 (66.7)</td>
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<tr>
<td>Muscle spasms</td>
<td>30 (12.0)</td>
<td>18 (7.1)</td>
<td>28 (11.1)</td>
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<tr>
<td>Diarrhea</td>
<td>18 (7.2)</td>
<td>18 (7.1)</td>
<td>36 (14.3)</td>
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<tr>
<td>Nausea</td>
<td>31 (12.4)</td>
<td>13 (5.1)</td>
<td>23 (9.1)</td>
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<tr>
<td>Vomiting</td>
<td>26 (10.4)</td>
<td>18 (7.1)</td>
<td>19 (7.5)</td>
</tr>
<tr>
<td>Headache</td>
<td>18 (7.2)</td>
<td>20 (7.9)</td>
<td>20 (7.9)</td>
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<tr>
<td>Hypocalaemia</td>
<td>18 (7.2)</td>
<td>1 (0.4)</td>
<td>17 (6.7)</td>
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<tr>
<td>Hypertension</td>
<td>12 (4.8)</td>
<td>17 (6.7)</td>
<td>19 (7.5)</td>
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<tr>
<td>Hypotension</td>
<td>16 (6.4)</td>
<td>10 (3.9)</td>
<td>14 (5.6)</td>
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<td>Arteriovenous fistula site complication</td>
<td>13 (5.2)</td>
<td>14 (5.5)</td>
<td>16 (6.3)</td>
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<td>Pain in extremity</td>
<td>17 (6.8)</td>
<td>11 (4.3)</td>
<td>7 (2.8)</td>
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<td>Paresthesia</td>
<td>13 (5.2)</td>
<td>3 (1.2)</td>
<td>11 (4.4)</td>
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<td>Back pain</td>
<td>8 (3.2)</td>
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<td>14 (5.6)</td>
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<td>Upper respiratory tract infection</td>
<td>8 (3.2)</td>
<td>10 (3.9)</td>
<td>13 (5.2)</td>
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</table>
Effect of Etelcalcetide vs Cinacalcet on Serum Parathyroid Hormone in Patients Receiving Hemodialysis With Secondary Hyperparathyroidism
A Randomized Clinical Trial

Geoffrey A. Block, MD; David A. Bushinsky, MD; Sunfa Cheng, MD; John Cunningham, MD; Bastian Dehmel, MD; Tilman B. Drueke, MD; Markus Ketteler, MD; Reshma Kewalramani, MD; Kevin J. Martin, MB, BCH; Sharon M. Moe, MD; Utpal D. Patel, MD; Justin Silver, MD; Yan Sun, MS; Hao Wang, PhD; Glenn M. Chertow, MD, MPH
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Geoffrey A. Block, MD; David A. Bushinsky, MD; Sunfa Cheng, MD; John Cunningham, MD; Bastian Dehmel, MD; Tilman B. Druke, MD; Markus Ketteler, MD; Reshma Kowdley, MD; Kevin J. Martin, MB, BCh; Sharon M. Moe, MD; Ujjal D. Patel, MD; Justin Silver, MD; Yan Sun, MS; Hao Wang, PhD; Glenn M. Chertow, MD, MPH

Table 2. Treatment Emergent Adverse Events*

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Patients, No. (%)</th>
<th>Etelcalcetide (n = 338)</th>
<th>Cinacalcet (n = 341)</th>
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<tr>
<td>Blood calcium decreased*</td>
<td>233 (68.9)</td>
<td>204 (59.8)</td>
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<tr>
<td>Nausea</td>
<td>62 (18.3)</td>
<td>77 (22.6)</td>
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<tr>
<td>Vomiting</td>
<td>45 (13.3)</td>
<td>47 (13.8)</td>
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<tr>
<td>Hypotension</td>
<td>23 (6.8)</td>
<td>10 (2.9)</td>
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<tr>
<td>Headache</td>
<td>22 (6.5)</td>
<td>24 (7.0)</td>
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<tr>
<td>Muscle spasms</td>
<td>22 (6.5)</td>
<td>20 (5.9)</td>
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<tr>
<td>Diarrhea</td>
<td>21 (6.2)</td>
<td>35 (10.3)</td>
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<tr>
<td>Hypertension</td>
<td>21 (6.2)</td>
<td>23 (6.7)</td>
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<tr>
<td>Anemia</td>
<td>17 (5.0)</td>
<td>15 (4.4)</td>
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<tr>
<td>Hypocalcemia</td>
<td>17 (5.0)</td>
<td>8 (2.3)</td>
<td></td>
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<tr>
<td>Pain in extremity</td>
<td>17 (5.0)</td>
<td>14 (4.1)</td>
<td></td>
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<tr>
<td>Bronchitis</td>
<td>5 (1.5)</td>
<td>17 (5.0)</td>
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</table>

* Adverse events occurring among 5% or more patients in either group. The term treatment emergent refers to a condition either not present before exposure to a study drug that develops after drug exposure or a condition present before exposure that worsens in frequency or severity. Adverse events occurring after the first dose of study drug and up to 30 days after the last dose of study drug were included. Counts and proportions refer to patients rather than to adverse events. In other words, patients may have one or more adverse event.

* Defined as an albumin-corrected serum calcium concentration lower than 8.3 mg/dL (to convert to mmol/L, multiply by 0.25) that resulted in a medical intervention.
A phase 3, multicentre, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of etelcalcetide (ONO-5163/AMG 416), a novel intravenous calcimimetic, for secondary hyperparathyroidism in Japanese haemodialysis patients

Masafumi Fukagawa1, Keitaro Yokoyama1, Takashi Shigematsu2, Takashi Akiba3, Akifumi Fujii4, Takuto Kuramoto5, Motoi Odani6, Tadao Akizawa7 and the ONO-5163 Study Group

1Division of Nephrology, Endocrinology and Metabolism, Department of Internal Medicine, Tokai University School of Medicine, Isehara, Japan, 2Division of Nephrology and Hypertension, Department of Internal Medicine, The Jikei University School of Medicine, Tokyo, Japan, 3Division of Nephrology, Department of Internal Medicine, Wakayama Medical University, Wakayama, Japan, 4Sekiyu Hospital, Tokyo, Japan, 5Clinical Development Planning, Data Science, Ono Pharmaceutical Co. Ltd. Osaka, Japan and 6Division of Nephrology, Department of Medicine, Showa University School of Medicine, Tokyo, Japan

Correspondence and offprint requests to: Masafumi Fukagawa; E-mail: fukagawa@tokai-u.jp

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FIGURE 3: Serum iPTH (A), cCa (B) and P (C) levels during the study period. Data are expressed as means ± standard deviation. *P < 0.05 regarding per cent changes from baseline compared with placebo.
FIGURE 4: Serum BAP (A) and TRACP-5b (B) levels during the study period. Data are expressed as means ± standard deviation.

FIGURE 5: Serum iFGF23 levels during the study period. Data are expressed as median (Q1, Q3).
In 2015, Bell et al.\textsuperscript{62} reported on results of a multicenter, double-blind, randomized, placebo-controlled, dose-escalating trial. This Phase II study included 78 hemodialysis patients with baseline PTH levels $\geq 350$ pg/mL. Subjects were divided into three cohorts: patients in cohort 1 received either 5 mg etelcalcetide or placebo thrice weekly after each hemodialysis session for 4 weeks, and those in cohorts 2 and 3 were treated with 10 mg or 5 mg etelcalcetide or placebo at the end of each dialysis for 4 weeks. The primary end point for cohorts 2 and 3 was defined as mean percentage change in PTH levels from baseline. After 4 weeks, PTH had decreased significantly by 49.4\% with 10 mg of etelcalcetide and by 33.0\% with 5 mg. The proportion of patients with $\geq 30\%$ PTH reduction was 76.2\% in etelcalcetide-treated patients vs 9.5\% in the placebo group ($P<0.0001$). Treatment with etelcalcetide was also associated with a decrease in serum-calcium and FGF23 levels. Approximately 40\% of study participants reported at least one treatment-emergent adverse event (TEAE), but the incidence of TEAEs was not dose-dependent and no patient discontinued the study due to a TEAE.

To date, no controlled studies directly comparing etelcalcetide with placebo, cinacalcet, or surgical parathyroidectomy with regard to hard clinical end points, such as mortality, cardiovascular events, fractures and parathyroidectomy in patients with ESKD have been conducted. The same holds true for parathyroidectomy, which has never been compared to calcimimetics in an RCT. This renders
After 2 months notification the new second-generation calcimimetic etelcalcetide effectively reduces PTH, Ph with an acceptable safety profile.

Hopefully at the end of our study protocol we will reach to more solid conclusions regarding better control of SHPT.
Agenda Style

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Secondary hyperparathyroidism (sHPT)

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<th>Name (am)</th>
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Control Ca
- Control intake
- Adjust dialysate Ca
- Use Ca supplements or vitamin D therapy (if Ca low)
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**Treatment of secondary hyperparathyroidism: the clinical utility of etelcalcetide**

Under normal physiological conditions (Figure 1), the principal regulator of PTH secretion and parathyroid gland function is the calcium-sensing receptor (CaSR). Activation of the CaSR by serum calcium rapidly inhibits PTH synthesis and secretion and parathyroid gland growth. Furthermore, the CaSR influences PTH gene expression and may also upregulate the vitamin D receptor (VDR).
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