

Routine cinacalcet for end stage kidney disease not warranted

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Cinacalcet, a drug commonly given to patients with end stage kidney disease to help keep phosphorus and parathyroid blood levels within a target range and has few patient level clinical benefits and several adverse effects, suggesting that it should no longer be routinely prescribed, according to a study by international researchers published in this week's *PLOS Medicine*.

These findings are important as cinacalcet has become the largest single drug cost for patients on dialysis in the US, with an annual expenditure of at least US \$260 million. In the UK, prescribing costs for this drug increased by up to 33% from 2010 to 2011, with no improvement in the survival of these patients.

In an analysis led by Giovanni Strippoli, an academic at the University of Sydney in Australia and a senior medical and research executive at Diaverum (a provider of renal services), the researchers examined the clinical effects of cinacalcet in almost 7500 patients by combining the findings from previous <u>randomized controlled trials</u>.

They found that compared to placebo or no treatment, cinacalcet had little or no effect on of the risk of death by any cause in people in the final stage of chronic kidney disease and unclear effects on death by any cause in people in the less severe stages of disease. Cinacalcet also had uncertain effects on <u>cardiovascular mortality</u> and <u>fracture prevention</u> in patients with late stage disease. All these are the primary reasons why its use has been long suggested and why large scale studies have been



performed.

Now performed, these studies shown no <u>survival advantage</u> and the authors also found that cinacalcet had significant side effects such as increased risk of hypocalcemia, nausea, vomiting and diarrhea but reduced the risk of hypercalcemia and prevented the need for surgical parathyroidectomy in people with end stage disease.

Overall, they concluded that on average, routinely treating 1000 people with cinacalcet for 1 year has no effect on death, but might prevent 3 people from experiencing surgical parathyroidectomy and leads to approximately 60 and 150 people experiencing hypocalcemia and nausea, respectively.

The authors say: "cinacalcet therapy provides small reductions in the risk of surgical parathyroidectomy but has little or no effect on all-cause mortality and uncertain effects on cardiovascular death for people with chronic kidney disease and is commonly associated with nausea and vomiting."

They continue: "Routine use of cinacalcet therapy in people with <u>chronic</u> <u>kidney disease</u> does not appear warranted, and benefits may be limited to preventing parathyroidectomy in the small number of patients for whom surgery is contraindicated."

More information: Palmer SC, Nistor I, Craig JC, Pellegrini F, Messa P, et al. (2013) Cinacalcet in Patients with Chronic Kidney Disease: A Cumulative Meta-Analysis of Randomized Controlled Trials. PLoS Med 10(4): e1001436. <u>doi:10.1371/journal.pmed.1001436</u>

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