ers each year (7.2 versus 4.7 visits, re-
respectively, but they visited those in the control
group (2.8 versus 3.7, respectively).

Study was underpowered for
primary outcome
Dr. van Zuijen explained the lack of a significant difference in the primary outcome as a result of too few CV events occurring, with a 5-year event incidence rate of 8.9 percent in both arms. When the study was planned, the estimated event rate in the control arm was 15.5 percent, based on the results of previous studies.

Johannes Mann, MD, of the depart-
ment of nephrology at Munich General Hospital in Munich, Germany, said he calculated that to be sufficiently pow-
tered to show a difference in the primary endpoint, the study would have required 10 times the number of individuals in-
volved in the MASTERPLAN trial.

In explaining the results, Dr. van Zuijen further noted that perhaps not all the treatment goals were beneficial, and that possibly, because some of the risk factors were well controlled in both groups, the differences between groups were small.

He concluded that nurse practitioner-

er can perform as well as physicians to improve CV risk factors if they follow established guidelines and that they "can then take away some of the burden of the very big patient loads we have in our outpatient departments."

Despite MASTERPLAN being un-
derpowered to show an effect between groups in the primary outcome of CV death, myocardial infarction, and stroke, Dr. Mann commented to ASN Kidney News that it was "a very important study because... the nurse practitioner inter-
vention was, in absolute terms, effective in reducing the primary outcome, which was a huge success."
Parathyroid Hormone

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oral stratum, 495 pg/mL and 510 pg/mL for the paricalcitol and cinacalcum arms, respectively). Comorbidities were common and possibly related to the characteristics of the larger population of patients receiving hemodialysis. Significantly more participants in the paricalcitol group iv stratum had type 1 diabetes, and those in the oral stratum had more type 2 diabetes.

Paricalcitol was initially dosed at 0.07 µg/kg iv or PTH/80 orally. The cinacalcet dose was 30 mg initially. The study inclusion criteria were hemodialysis three times a week for at least three months before entry; an iPTH level between 300 and 800 pg/mL inclusive; a calcium level of 8.4–10.0 mg/dL; and phosphorus at or below 6.5 mg/dL at baseline.

The primary outcome of the trial was the proportion of participants attaining a mean iPTH value of 150–300 pg/mL during weeks 21 to 28 (normal iPTH is 10–65 pg/mL). A secondary outcome was the proportion of participants with hypocalcemia, defined as a mean serum calcium level of less than 8.4 mg/dL, or with hypercalcemia, defined as a mean calcium level of at least 10.5 mg/dL.

More people receiving paricalcitol achieved iPTH target

In the primary efficacy analysis of reaching the target iPTh level, iv paricalcitol was superior to iv cinacalcet, with fewer patients outside the normal serum calcium range. In the iv stratum, 58 percent of patients receiving paricalcitol achieved the iPTh endpoint versus 33 percent receiving cinacalcet (p = 0.016). However, the patients taking the oral drugs showed no significant difference in the proportion achieving the iPTh target (54 percent with paricalcitol versus 43 percent with cinacalcet; p = 0.26).

In a secondary efficacy analysis that controlled for strata, paricalcitol was superior to cinacalcet, with 56 percent and 58 percent of participants, respectively, falling in the iPTh efficacy range during the evaluation period (p = 0.01).

When the wholesale costs in the United States of paricalcitol, cinacalcet, and vitamin D preparations were calculated, the medication costs for paricalcitol treatment were 40 percent lower than for cinacalcet treatment.

Adverse events

Hypocalcemia occurred in about half of the cinacalcet patients in either the iv or the oral stratum but in only 4 percent in the oral paricalcitol stratum and in none in the iv stratum. Minimal hypercalcemia was observed and was not significantly different between the two drugs taken either iv or orally.

In all, 69–81 percent of subjects in the four groups completed the study. Serious adverse events led to interruption of the study drugs in 22–27 percent of the patients in any of the four arms. When the iv and oral strata were combined, three times as many major adverse cardiovascular events occurred with paricalcitol (9/134) than with cinacalcit (3/134), possibly because of differences in risk factors between the groups at baseline.

In conclusion, Dr. Ketteler said “Paricalcitol showed superior outcomes over cinacalcit in achieving the primary efficacy endpoint” when strata were controlled for. He noted that hypocalcemia occurred in almost half of the patients treated with cinacalcit and that in paricalcitol-treated patients the incidence of hypercalcemia was not significantly different from that in people treated with cinacalcit.