



Jan 28, 2021

DPP4

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dx.doi.org/10.17504/protocols.io.brvtm66n

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DOI

dx.doi.org/10.17504/protocols.io.brvtm66n

DOCUMENT CITATION

thananda 2021. DPP4. **protocols.io**
<https://dx.doi.org/10.17504/protocols.io.brvtm66n>

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CREATED

Jan 28, 2021

LAST MODIFIED

Jan 28, 2021

DOCUMENT INTEGER ID

46739

Sample Size Calculation:

Choi et al reported the reduction of reactive oxygen species (NADPH Oxidase, NOX 4) by gemigliptin for 340 units. By using independent formula with related samples, therefore

$$Z\alpha = Z \text{ value at level of significance } 0.05 = 1.960$$

$$Z\beta = Z \text{ value at level of significance } (0.2) = 0.840$$

$$2d = \text{Variance of reactive oxygen species before and after gemigliptin treatment}$$

$$M1 - M0 = \text{Difference of reactive species before and after gemigliptin treatment} = 340$$

$$n =$$

$$n = 100$$

Since this is the first study for gemigliptin for this outcome, the target number of enrolled patients was set at 100

Reference:

Choi S,Ryu H,Oh E,Choi J,Cho J,Kim C,Kim Y,Park S.Dipeptidyl peptidase 4 inhibitor gemigliptin protevts against vascular calcification in an experimental chronic kidney disease and vascular smooth muscle cell. PLoS One 2017;12(7):e0180393

Method of randomization

After enrollment, eligible patients will be randomized (1:1) by systemic random samplingby the study coordinator to either gemigliptin or control group,using envelop containing letter A or B , 2 of each letter in one envelop. Therefore one envelop will have 2 pairs of each letter such ,ABAB or BABA while A represents gemigliptin and B means control. The patients were blinded to the allocation. Only the predesigned study person will have access to the sealed randomization.