

EudraCT number

2017-002739-40

Full title of trial

Beta cell imaging in type 1 diabetes with stable near-normal and unstable glucose control

Results

Participants with stable glucose control had a lower HbA_{1c} (46 ± 1.9 vs 80 ± 10.9 mmol/mol, $p=0.001$) and a higher time in range (TIR) measured with a glucose sensor (75.6 ± 5.7 vs 38.7 ± 4.8 %, $p=0.002$) than the participants with unstable glucose control. Quantification of the acquired PET/CT images demonstrated a higher pancreatic SUVmean (measure for beta cell mass) for participants with stable glucose control compared to those with unstable glucose control (5.1 [3.6 - 5.6] vs. 2.9 [2.1 - 3.4], $p=0.008$). The area under the curve (AUC) for C-peptide was higher in the group with stable glucose control (44.6 [1.2 - 90.6] vs. 1.2 [1.2 - 12.8] nmol·min/L, $p=0.21$). SUVmean correlated with the AUC for C-peptide (Pearson $r = 0.62$, $p=0.01$), as well as with the TIR ($r=0.64$, $p=0.01$) and the standard deviation of interstitial glucose levels ($r=-0.66$, $p=0.007$).

Conclusion

These data show higher beta cell mass in people with type 1 diabetes and stable glucose control than in people with unstable glucose control. Although there was a correlation between beta cell mass and function, some individuals with stable glucose control had sufficient beta cell mass without measurable function. In summary, the findings in this trial support that preservation of beta cell mass additionally benefits glycemic stability in people with type 1 diabetes alongside beta cell function.

Total number of included participants

The sample size of 18 subjects (9 per group) was determined using the data acquired in a previous study with exendin SPECT (1). Because the inclusion of subjects with an unstable glucose control was challenging, seven individuals were included in this group instead of nine, yet this was considered acceptable provided that the better spatial resolution and improved image quantification of PET would allow for better detection of small differences in pancreatic uptake compared to SPECT.

References

1. Brom M, Woliner-van der Weg W, Joosten L, Frielink C, Bouckennooghe T, Rijken P, et al. Non-invasive quantification of the beta cell mass by SPECT with (1)(1)(1)In-labelled exendin. Diabetologia. 2014;57(5):950-9.