primary studies - published RCT

Slow-release insulin in cystic fibrosis patients with glucose intolerance: a randomized clinical trial.

Code: PM22060105 **Year:** 2011 **Date:** 2011 **Author:** Minicucci L

Study design (if review, criteria of inclusion for studies)

phase 3 multicenter, controlled, two-arm, randomized clinical study

Participants

subjects with early stages of glucose metabolism impairment

Interventions

glargine was administered up to a dosage of 0.15 U/kg/die for a period of 18 months

Outcome measures

Primary endpoint was the improvement of nutritional status [body mass index (BMI) Z score], while glucose tolerance [hemoglobin A1c (HbA1C) and respiratory function (FEV1 predicted] improvement were the secondary endpoints

Main results

Thirty-four subjects (18 in the glargine arm and 16 in the control arm) were evaluated. Adherence to insulin treatment was excellent. No significant adverse events were reported. There were no significant differences in BMI, HbA1C and FEV1 values between the two groups nor within groups, except for HbA1C improvement in the glargine arm at month +18 ($p = 0.04$)

Authors' conclusions

Glargine treatment was well accepted and tolerated. No real efficacy in improving clinical and glycometabolic conditions was demonstrated. Further studies are necessary to test glargine at higher dosage and for a longer follow-up period.

http://dx.doi.org/10.1111/j.1399-5448.2011.00810.x

See also

Pediatr Diabetes. 2012 Mar;13(2):197-202. doi: 10.1111/j.1399-5448.2011.00810.x. Epub 2011 Nov 8.

Keywords

Glargine; Insulin; Hypoglycemic Agents; pharmacological_intervention; Glucose Intolerance; Pancreatic Diseases; Gastrointestinal Diseases;