Date: 2021-02-11

Summary attachment - study ended before 21 July 2013

EudraCT number: 2007-003963-31

Full title of the study: A three months, double-blind, randomized, parallell-group study evaluating the efficacy of sitagliptin (Januvia®) versus placebo on beta-cell function in patients with newly detected glucose abnormalities and acute myocardial infarction or unstable angina

Sponsor: Karolinska Institutet

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Study ended: 2010-11-30

Link to published article: https://onlinelibrary.wiley.com/doi/full/10.1111/joim.12032

Abstract from published article:
Background: Newly detected impaired glucose tolerance (IGT) or type 2 diabetes mellitus (T2DM) are common in patients with acute coronary syndrome (ACS; i.e. unstable angina/myocardial infarction) and related to disturbed beta-cell function. The aim of this study is to test the hypothesis that treatment with a dipeptidyl peptidase-4 inhibitor initiated soon after a coronary event improves beta-cell function.
Methods: Acute coronary syndromeACS patients with IGT or T2DM (n = 71), screened by oral glucose tolerance test (OGTT) 4–23 days (median 6 days) after hospital admission, were randomly assigned to sitagliptin 100 mg (n = 34) or placebo (n = 37) and treated for a duration of 12 weeks. All patients received lifestyle advice but no glucose-lowering agents other than the study drug. The study end-point was beta-cell function assessed using the insulinogenic index (IGI = ΔInsulin30/ΔGlucose30), derived from an OGTT, and acute insulin response to glucose (AIRg) assessed by a frequently sampled intravenous glucose tolerance test.
Results: The IGI and AIRg did not differ at baseline between the sitagliptin and placebo groups (69.9 vs. 66.4 pmol mmol−1 and 1394 vs. 1106 pmol L−1 min−1 respectively). After 12 weeks, the IGI was 85.0 in the sitagliptin and 58.1 pmol/mmol in the placebo group (P = 0.013) and AIRg was 1909 and 1043 pmol L−1 min−1 (P < 0.0001) in the sitagliptin and placebo groups respectively. Fasting glucose at baseline was 6.1 mmol L−1 in sitagliptin-treated patients and 6.0 mmol L−1 in those who received placebo compared with 5.8 and 5.9 mmol L−1 respectively, after 12 weeks of treatment. Post load glucose metabolism improved in significantly more sitagliptin-treated patients compared with the placebo group (P = 0.003). Sitagliptin was well tolerated.

Conclusion: Sitagliptin improved beta-cell function and glucose perturbations in patients with ACS and newly diagnosed glucose disturbances.

Links to articles related to the secondary aims:
https://journals.sagepub.com/doi/10.1177/1479164114533355?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed&

https://journals.sagepub.com/doi/10.1177/2047487312444371?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

Registered in ClinicalTrials.gov: NCT00627744

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