

Research Project

Screening of gestational diabetes mellitus in early pregnancy by oral glucose tolerance test and glycosylated fibronectin: an international, prospective, multi-centre cross-sectional study

Third-party funded project

Project title Screening of gestational diabetes mellitus in early pregnancy by oral glucose tolerance test and glycosylated fibronectin: an international, prospective, multi-centre cross-sectional study

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As the accurate diagnosis and treatment of gestational diabetes mellitus (GDM) is of increasing importance, new diagnostic approaches for the assessment of GDM in early pregnancy were recently suggested. We evaluate the diagnostic power of an "early" oral glucose tolerance test (OGTT) 75g and glycosylated Fibronectin (glyFn) for GDM screening in a normal low-risk population.METHODS: In a prospective cohort study, 748 singleton pregnancies will be recruited in six centres in Switzerland, Austria and Germany. Women will be screened for pre-existing diabetes mellitus and GDM by an "early" OGTT 75g and/or the new biomarker, glyFn, at 12 to 15 weeks of gestation. Different screening strategies are compared to evaluate the impact on detection of GDM by an OGTT 75g at 24 to 28 weeks of gestation as recommended by the International Association of Diabetes and Pregnancy Study Groups (IADPSG).EXPECTED OUTCOME: The diagnostic accuracy of glyFn and "early" OGTT 75g will be assessed. A new screening algorithm will be created by using multivariable risk estimation incorporating maternal risk factors. ETHICS AND DISSEMINATION: This study has received ethical approval from the ethics committees in Basel, Zurich, Vienna, Salzburg and Freiburg. Data will be presented at international conferences and published in peer-reviewed journals.REGISTRATIONS: The pilot study was first registered under www.ClinicalTrials.gov in 2014. Project partners were added and changes to study design were reported in 2016. Project identification code is NCT02035059.

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