

Participating centers



Partners

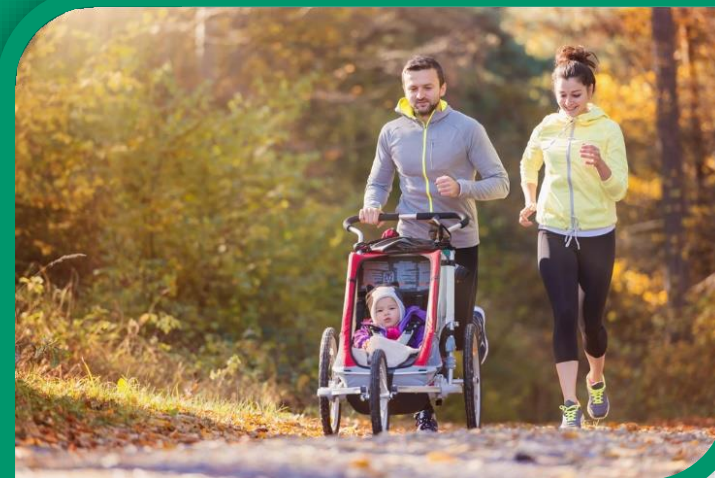


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serena

Have you recently been diagnosed with gestational diabetes? Do you still have elevated sugar levels shortly after delivery?

The SERENA project is investigating whether we can prevent type 2 diabetes with the medication Ozempic® in women who have elevated sugar levels (prediabetes) after a recent pregnancy with gestational diabetes.



Principal investigator: Prof. Katrien Benhalima

Study S66967, approval by an Independent Ethics Committee.

Why are we doing this study?

The purpose of this study is to determine whether the drug semaglutide (brand name Ozempic®) can reduce the risk of developing diabetes in women with elevated sugar levels (prediabetes) following a recent pregnancy with gestational diabetes. Women who already have prediabetes within 6 months after the delivery have a particularly high risk, as about 50% will develop type 2 diabetes within 5 years of the delivery.

What is the SERENA study about?

Semaglutide is used to treat people with type 2 diabetes. It has been shown in individuals with type 2 diabetes that treatment with semaglutide can lower sugar levels and is often also associated with weight loss and a lower risk of cardiovascular disease.

You should not participate in the study if you:

- ❖ Are still breastfeeding >22 months after delivery
- ❖ Wish to become pregnant within 1,5 years
- Because the effects of semaglutide on an unborn child or baby are not yet known.

What does the SERENA study consist of?

To identify elevated sugar levels in a timely manner, a comprehensive fasting sugar test (OGTT) is done in women who have had gestational diabetes in the normal routine between 6 weeks and 12 months after delivery. If this test shows elevated sugar levels (prediabetes), you will be invited to participate in this study. A computer system will randomly decide whether you will be assigned to the group treated with semaglutide or with the inactive product (placebo) (1/1 randomization). Neither the researchers, the treating physician nor you yourself will know whether you are receiving semaglutide or placebo. Both semaglutide and placebo will be administered by subcutaneous injection once a week (in the abdomen, thigh -or arm). You will be taught to self-administer the injection.

Regardless of which group you are assigned to:

- ❖ You will have a fasting blood draw every 6 months and an annual fasting sugar test (OGTT) with blood draw, lifestyle education, physical examination and questionnaires to answer.
- ❖ Treatment will last up to 3 years.
- ❖ 3-6 months after the treatment has ended, there will be another fasting sugar test (OGTT) with blood sampling, lifestyle education, physical examination and questionnaires to answer.

You will receive limited compensation for your participation.

Are you interested in participating?

If so, please contact the participating hospitals.

www.serenaproject.be