

BASISPROTOCOL


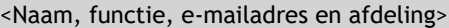
OPZETTEN DATABANK

AMSTERDAM UMC

PROTOCOL

Versiedatum	19-12-2024
Versienummer	1.6
Verwerkingsregister-nummer	188282

ALGEMENE GEGEVENS

Titel databank	Diabetes in Pregnancy Registry
Acroniem databank	DiaPregNL
Indiener	Veronika Duwel, PhD Kandidaat, v.duwel@amsterdamumc.nl
Beheerder databank	<p>Wie gaat de databank beheren? (s.v.p. <i>aankruisen wat van toepassing is</i>)?</p> <p><input checked="" type="checkbox"/> Principal investigator</p> <p> Sarah E. Siegelaar, internist-endocrinoloog, s.e.siegelaar@amsterdamumc.nl</p> <p><input type="checkbox"/> Anders (bijvoorbeeld RDM) nl: </p>
Locatie Databank	Castor
Type gegevens	<p>Wat voor soort data wordt in de databank opgeslagen (s.v.p. <i>aankruisen wat van toepassing is en waar nodig beschrijven</i>)?</p> <p><input checked="" type="checkbox"/> Gegevens uit het medisch dossier</p> <p><input type="checkbox"/> Whole genomes of whole exome</p> <p><input type="checkbox"/> GWAS, EWAS, DNA-profiles of enkele genen/mutations</p> <p><input type="checkbox"/> Methylation, SNP's, knockouts/deletions</p> <p><input type="checkbox"/> Beeldvorming van het hoofd of beeldvorming inclusief hoofd</p> <p><input type="checkbox"/> Foto's van het hoofd of foto's inclusief hoofd</p> <p><input type="checkbox"/> Geluidsopnames</p> <p><input type="checkbox"/> Video inwendig</p> <p><input type="checkbox"/> Video</p> <p><input checked="" type="checkbox"/> Vrije tekst</p> <p><input type="checkbox"/> Locatie data zoals GPS of andere tracking data</p> <p><input type="checkbox"/> Zeldzame aandoening</p> <p>Gegevens verzameld tijdens een afspraak bij zwangeren met diabetes spreekuur o.a. diabetes type, co-morbiditeiten,</p>

	medicatie, lab waarden, informatie uit glucose monitoring systemen
Koppeling aan een (niet-) WMO-plichtige studie?	Nee

ACHTERGROND EN DOEL

Rationale	<p>Living with diabetes poses significant challenges, particularly for women planning pregnancy or already pregnant. In the Netherlands, approximately 800 women with pre-existent diabetes become pregnant annually (1), requiring strict glucose control to prevent adverse pregnancy outcomes. Despite advancements in diabetes technology, many struggle to achieve recommended glucose targets, facing increased risks of maternal and neonatal complications such as congenital malformations, stillbirth, preterm birth, or hypertensive disorders of pregnancy, compared to women without diabetes (2,3). The need for strict glucose control is often accompanied by fear of hypoglycemia and impaired quality of life bringing up feelings of incompetence, guilt, or loneliness for these women.</p> <p>The only study in the Netherlands studying perinatal maternal and fetal outcomes in relation to diabetes was conducted over 20 years ago and focused solely on women with type 1 diabetes (4). Since then there have been many changes in healthcare system and delivery, such as wide adaptation of diabetes technology (long-acting insulin analogues, insulin pump, and continues glucose monitoring). Many trials have been set up to study the effects of new technology on glycemic targets during pregnancy (ex. CONCEPTT trial (2)), while the results are promising, achieving target glucose throughout pregnancy remains a challenge for many. First published study on the newest diabetes technology (hybrid closed loop) in pregnancy shows a vast improvement in glucose targets, yet these improvements have been achieved in only 47% of the participants (5).</p> <p>Studying technology alone however misses many important factors which could contribute to poor outcomes in pregnancy for people with diabetes. Outcomes may be influenced by education, health care access and quality, economic stability, physical environment, and social context (6).</p> <p>In order to look for barriers to improving glucose regulation and find aspects of care which require optimization, it is necessary to have solid data on current prevalence of pregestational diabetes in pregnancy, complication frequency, and uptake of diabetes technology. While a lot of data is already stored in patient files, it is not available for research in a structured way. Furthermore, this registry presents the opportunity to study both the mothers and children long-term as little is known of long-term impact of diabetes treatment during pregnancy on the offspring (7,8). The long term effects of</p>
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	diabetes have been studied extensively, this data would greatly add to our knowledge of the impact of both pregnancy and diabetes on human body (9).
Doel	<p>Our goal is to gather the already available data about diabetes care during pregnancy, complications of diabetes and of pregnancy, complications of children, and patients experience in the current healthcare system by the means of a new national registry for women with diabetes in pregnancy. Our comprehensive data collection and long-term storage will create opportunity to follow outcomes over the years, gain insight in the quality of healthcare, identify best practices, and share our findings by writing best practice protocols.</p> <p>The outcome gap is still significant between pregnant women with and without pre-gestational diabetes (8), with this registry we aim to improve health outcomes for pregnant women with diabetes and their children in the Netherlands.</p>
Lekensamenvatting	<p>Diabetes brengt grote uitdagingen met zich mee, vooral voor vrouwen die zwanger willen worden of al zwanger zijn. Geschat wordt dat in Nederland jaarlijks ongeveer 800 vrouwen met pre-existente diabetes zwanger raken. Het is belangrijk dat deze vrouwen hun bloedsuikerspiegel goed onder controle houden om complicaties tijdens de zwangerschap te voorkomen, zoals aangeboren afwijkingen en vroeggeboorten. Ondanks de vooruitgang in diabetestecnologie hebben veel vrouwen moeite om hun bloedsuikers binnen de aanbevolen waarden te houden, wat kan leiden tot meer complicaties, een slechtere kwaliteit van leven en gevoelens van onbekwaamheid en eenzaamheid. In Nederland is al meer dan 20 jaar geen onderzoek gedaan naar de gevolgen van diabetes tijdens de zwangerschap, terwijl er sindsdien veel veranderingen hebben plaatsgevonden in de gezondheidszorg en technologie.</p> <p>Om de huidige situatie in kaart te brengen, willen we een landelijk register opzetten voor zwangeren met pre-existente diabetes. Met dit register verzamelen we gegevens over diabeteszorg tijdens de zwangerschap, complicaties voor moeders en kinderen, en ervaringen van patiënten binnen het huidige zorgsysteem. Alle data die we verzamelen, worden normaal gesproken al vastgelegd tijdens afspraken in het kader van reguliere zorg en we veranderen niets aan de normale zorgverlening. Er is één verplichte vragenlijst over basale kenmerken, die minder dan 3 minuten duurt.</p> <p>Daarnaast ontvangen deelnemers optionele vragenlijsten over kwaliteit van leven, sociaaleconomische status en zorgervaring, die vier keer tijdens de zwangerschap en postpartum worden verzonden. De totale tijdsinvestering bedraagt maximaal 20 minuten.</p> <p>Door langdurige opslag en de mogelijkheid om de gegevens van de deelnemers te koppelen aan andere registraties, bieden we ook kansen om meer inzicht te krijgen in de langetermijneffecten van diabetesbehandeling tijdens de zwangerschap voor moeder en kind. Deze informatie kunnen we</p>

	<p>gebruiken om landelijke protocollen te ontwikkelen voor de behandeling van diabetes tijdens de zwangerschap en om via het register het effect van nieuwe protocollen op de populatie te monitoren.</p> <p>Ons doel is om beschikbare gegevens te verzamelen over diabeteszorg tijdens de zwangerschap, complicaties bij moeder en kind, en de ervaringen van patiënten. Dit willen we bereiken door een nieuw landelijk register op te zetten voor zwangeren met preexistente diabetes.</p>
Aard van toekomstige onderzoeksvragen	<p>What is the prevalence of pregnant women with diabetes in the Netherlands?</p> <p>What is the current complication rate for pregnant women with pre-gestational diabetes?</p> <p>Does pregnancy planning improve perinatal outcomes?</p> <p>Does having a specialized pregnancy team improve perinatal outcomes?</p> <p>Does use of diabetes technology lead to better perinatal outcomes?</p> <p>Does using diabetes technology lead to reduction of costs of care?</p> <p>Does the implementation of a national protocol improve perinatal outcomes?</p> <p>Have negative outcomes in children improved due to better care for pregnant women with diabetes?</p>

DEELNEMERS

Studiepopulatie	<p>Primary: Adult pregnant people with a diagnosis of diabetes mellitus before pregnancy.</p> <p>Secondary (with permission of one of the parents): The child(ren) of primary population.</p>
Inclusiecriteria	<ul style="list-style-type: none"> • Pregnant • > 18 years of age • Diagnosis of diabetes mellitus prior to pregnancy • Sufficient proficiency in Dutch or English to understand verbal and written information.
Exclusiecriteria	<ul style="list-style-type: none"> • No consent given • Not legally competent (wilsonbekwaam)
Aantal deelnemers	<p>Current estimates are that around 800 women with pre-gestational diabetes get pregnant every year. In the first year we will conduct a pilot program in 11 hospitals. With an average of 12 patients per hospital per year we aim to achieve around 130 (±15) participants in the first year. In the following years we hope to efficiently include all Dutch hospitals and aim to have around 800 participants per year.</p>
Werving deelnemers	<p>All women will be recruited by their healthcare providers at department of internal medicine of participating hospitals. Vast majority of participants will be already patients there. If they are not (ex. low risk type 2 diabetes patient who receives follow up in first line, or type 1 diabetes patient who receives care in a diabetes clinic), they should be referred to a hospital for pregnancy follow up, where the gynecologist should make a referral to the department of internal medicine.</p>

	<p>Pregnant women will receive verbal explanation, an informational brochure, and a link to the registry website for more information. To increase awareness of the project and accessibility of information forms, we are already collaborating with patient organizations (DVN, DiabetesPlus). Posters, flyers, and social media campaigns will be launched. In this way, pregnant women can also ask their healthcare provider if they are eligible to participate in the study. It is of relevance to add that this population is particularly motivated to see improvement in care.</p>
Toestemming deelnemer	<p><input checked="" type="checkbox"/> 'Specifieke toestemming gebruik gegevens voor onderzoek' (vereist bij gevoeg nader gebruik-onderzoek) (bewijsstuk: 'toestemmingsformulier nader-gebruik specifiek' of aantekening in EPD)</p>
Indien van deelnemer geen toestemming wordt verkregen	<p>NVT</p>
Informereren	<p>We will build a website where information about the registry will be publicly available. There will be dedicated sections for patients, healthcare providers, and other researchers. It will explain the purpose of the study, what happens to the data, how to participate, and how to withdraw from the registry. We will also share all publications of the research results there.</p> <p>In addition, participants can indicate on the consent form that they wish to receive emails about the progress of the study and the publication of the results. We will share our findings at national and international conferences and also publish in open-access journals. We will ask our partner patient organizations to publish our results on their respective websites and social media. If possible, we would like to share our results at the national level by writing articles for national newspapers and conducting interviews on national television.</p>
Belasting	<p>Since the main purpose of the registry is to collect available data, we expect minimal burden on participants. Majority of the data we request should be collected as part of a routine appointment with the diabetes nurse or internal medicine doctor. There is one mandatory questionnaire to gather baseline characteristics, including specifically ethnicity, among other details. It takes less than 3 minutes to fill it in. Perinatal outcomes will be obtained through data extraction from patient files, also without any burden on patients. Because no interventions are applied or new treatments are being tested, patients will not experience any negative consequences from participating in the database. On the contrary, we hope that the database will improve outcomes for patients, allowing participants to have a direct positive impact on future pregnant women, or even on themselves.</p> <p>Furthermore, participants will be sent short questionnaires regarding quality of life, socioeconomic status, social support, motherhood, breastfeeding, and experience of care. Participation in these questionnaires is not mandatory, participants can choose to fill in some and skip other questionnaires. The</p>

	<p>questionnaires will be sent four times at predetermined moments (pregnancy week 8-12, week 24-28, week 34-38, and 5-8 weeks postpartum). They have been tested by two volunteers from the target study population, both for understanding and the time commitment. The maximum total expected time is around 20 minutes, each taking on average 5 minutes or less.</p> <p>There is a significant burden on internal medicine team which will have to fill in the diabetes related data in the Castor database. We are already working with Research Data management and IT to see how we can make the data extraction automatic. Since the number of patients per hospital per year is low (estimated average of 12 per hospital), we expect that this method of data collection is still achievable in the short-term.</p>
Bewaartermijn	<p>We request an retention period of 15 years. After which we will evaluate the added benefit to retaining the gathered information every 5 years. As this is a databank, we hope the data will be useful in linking the pregnancy data to the long-term health outcomes of the both mother and child(ren).</p>

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