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WelZCaVa I wellbeing registry for pregnant women with cardiovascular disease

Submission date
07/11/2024

Recruitment status
Recruiting

Registration date
19/11/2024

Overall study status
Ongoing

Last Edited
03/07/2025

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Standardised monitoring of obstetric, maternal and fetal outcomes, as well as patient-reported outcomes and experiences (PROs and PREs), is needed to ensure that future recommendations take into account the needs and requirements of pregnant women with cardiovascular disease themselves. Currently, there is a lack of evidence on the impact of pregnancy in women with a cardiovascular profile on pregnancy outcomes. The development of a comprehensive patient registry combining clinical, maternal and fetal outcome measures, complemented by a validated set of PROs and PREs, is of paramount importance. There is also a need for scientific understanding of the relationship between these clinical outcomes and patient-reported outcome measures.
The aim of this study is to create a general registry for women with heart and/or vascular disease that will record clinical outcomes (such as disease-specific data and possible pregnancy complications), patient-reported outcomes, and experiences during and after pregnancy.

Who can participate?
Female patients with a current pregnancy who are being followed by a gynaecologist and/or cardiologist in the cardio-obstetrics department of one of the participating hospitals.

What does the study involve?
This study will collect data from medical records and questionnaires. Questionnaires will be sent digitally to participants, often a few days before their scheduled hospital appointment with their gynaecologist or cardiologist. These questionnaires will measure their experience of the care and support received during pregnancy and labour. These questionnaires will also measure how they feel (or felt) during this time.
In total, participants will be asked to complete questionnaires at three different times during their pregnancy: the first, second and third trimesters. They will also be asked to complete questionnaires at three different times after giving birth: in the first week, about 6 weeks, and about 12 weeks after giving birth.

What are the possible benefits and risks of participating?
Participation in the study is completely voluntary and participants have the right to refuse to take part in the study without this affecting their care in the hospital. They have the right to

withdraw from the study at any time, even after they have signed the consent form. They do not have to give a reason for withdrawing your consent to participate. Withdrawal will not result in any disadvantages or loss of benefits.
There are no specific risks associated with taking part in this study. However, it is possible that certain questions about experiences and/or feelings may trigger certain emotions or memories. For this reason, the questionnaires will also be prepared and analysed with the utmost care for the mental and emotional wellbeing and privacy of the participants. The researchers may refer study participants to appropriate psychological care if they feel this is desirable for their general and mental wellbeing, but this will always be done in close consultation with the patient.
If participants agree to take part in this study, the researchers cannot confirm that they will personally benefit directly. The results will help the researchers to understand the experiences, feelings and other outcomes of women with cardiovascular disease during and after pregnancy. Taking part in the study will help our healthcare team improve the advice and support they give to these women in the future. In order to achieve this goal, participation in this survey will be very valuable.

Where is the study run from?
University of Antwerp (UA) and the University Hospital Antwerp (UZA) in Antwerp, Belgium

When is the study starting and how long is it expected to run for?
July 2023 to December 2025

Who is funding the study?
University of Antwerp (Belgium)

Who is the main contact?
Prof. Eva Goossens, eva.goossens@uza.be

Study website
https://www.uantwerpen.be/en/research-groups/centre-for-research-innovation-care/research/research-projects/research-projects-pancard/welzcava/

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
5571

Study information

Scientific Title
Development of a registry of clinical, patient-reported outcomes and experiences for pregnant women with cardiovascular conditions

Acronym
WelZCaVa

Study objectives
Standardised monitoring of obstetric, maternal and fetal outcomes, as well as patient-reported outcomes and experiences (PROMs and PREMs), is needed to ensure that future

recommendations take into account the needs and requirements of pregnant women with cardiovascular disease themselves. Currently, there is a lack of evidence on the impact of pregnancy in women with a cardiovascular profile on pregnancy outcomes. The development of a comprehensive patient registry combining clinical, maternal and fetal outcome measures, complemented by a validated set of PROs and PREs, is of paramount importance. There is also a need for scientific understanding of the relationship between these clinical outcomes and patient-reported outcome measures.

This study, which is part of a PhD programme, aims to establish a multi-centre patient registry of pregnant women with acquired, hereditary or congenital cardiovascular disease, in which a range of obstetric, maternal and fetal outcomes, as well as PROMS and PREMS, will be collected during the perinatal and post-partum period (cf. 4th trimester). This study aims to:
1. Determine the impact of pregnancy through a range of maternal, obstetric and fetal/neonatal outcomes
2. Determine the impact of pregnancy through a range of patient-reported outcomes and experiences in the perinatal and post-partum period
3. Explore the associations between maternal, obstetric and fetal/neonatal outcomes and PROMS/PREMS in the perinatal and post-partum period

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 17/07/2023, Antwerp University Hospital (Drie Eikenstraat 655, Edegem, 2650, Belgium; +32 3 821 38 97; ethisch.comite@uza.be), ref: 5571

2. Approved 14/05/2024, University Hospital of Ghent (Corneel Heymanslaan 10, Gent, 9000, Belgium; +329 332 33 36; ethisch.comite@uzgent.be), ref: ONZ-2023-0567

3. Approved 13/06/2024, Ziekenhuis Aan de Stroom (Lindendreef 1, Antwerp, 2600, Belgium; +323 280 34 29; zna.ethische-commissie@zas.be), ref: 5571

4. Submitted 28/10/2024, Leuven University Hospital (Herestraat 49, Leuven, 3000, Belgium; +32 16 34 86 00; ec@uzleuven.be), ref: S68628

Study design
Prospective multicentre descriptive study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Female patients who are currently pregnant and being followed for congenital, hereditary or acquired cardiovascular disease

Interventions
Data are collected using the medical/electronic patient record and a set of questionnaires covering the selected PROMS and PREMS.

The registry will collect data from the first consultation at a tertiary centre up to and including 12 weeks after delivery (cf. fourth trimester). There will be at least four data collection points for each enrolled pregnant woman: at least one data collection point during the perinatal period, depending on the date of enrolment and current gestational age (cf. trimester 1, 2 or 3) and at least three data collection points during the postpartum period (see week 1-2, 4-6 and 6-12 postpartum). At each data point, questionnaires will be sent out asking about patient-reported outcomes and/or experiences. Clinical data will be collected once during the perinatal period and once during the postpartum period to monitor more general maternal and fetal outcomes.

Intervention Type
Other

Primary outcome measure
Patient-reported outcomes:
1. The possible presence of depressive symptoms is measured using the validated Whooley scale
2. The possible presence of an anxiety disorder is measured using the General Anxiety Disorder 7 questionnaire
3. Autonomy and shared decision-making are assessed using the Mothers on Autonomous Decision Making (MADM) scale
4. Social support is measured using the validated Oslo-3 scale
5. Empowerment is assessed using the validated Pregnancy Related Empowerment Scale (PRES)
6. Symptoms of possible (postnatal) depression, anxiety and suicidal ideation assessed using the Edinburgh Postnatal Depression Scale (EPDS)
7. Mother-infant bonding is assessed using the Mother-Infant Bonding Scale (MIBS). The validated Postpartum Bonding Questionnaire (PBQ) is also administered at the same time to ensure that mother-child bonding has been properly assessed.

Patient-reported experiences:
Patient satisfaction will be measured using the validated Maternity Satisfaction with Care Questionnaire (MSCQ) developed as part of the Born in Belgium study.

The registry will collect these data from the first consultation in a tertiary centre up to and including 12 weeks after delivery (cf. fourth trimester). For each enrolled pregnant woman, there will be at least 4 data collection points: at least 1 data collection point during the perinatal period, depending on the date of enrolment and the current gestational age (cf. trimester 1, 2 or 3) and at least 3 data collection points during the postpartum period (cf. week 1, 6 and 12 postpartum).

Figure 1 of the study protocol provides a visual overview of the respective data collection points for demographics and clinical outcomes. Figure 2 also provides a visual overview of the respective data collection points for the PROMS and PREMS datasets. It is important to note that the date of enrolment during the perinatal period is a highly variable element of the study, where the date of the patient's first registration at the outpatient clinic may vary between trimester 1, 2 or 3. During this perinatal period there will be at least one measurement time per participating patient. However, depending on the patient's exact enrolment date and gestational age, an attempt will be made to provide one data collection point per trimester. Ideally, however, the maximum number of measurement times (one measurement time per trimester) should be achieved, as shown in the figure.

Secondary outcome measures
The following set of obstetric, maternal and fetal/neonatal outcomes will be collected from the medical record once at 2 weeks postpartum:
1. The set of maternal and obstetric outcomes listed in Appendix 2 of the study protocol will consist of the following variables: maternal mortality, length of stay, haemorrhage; obstetric outcomes such as abruptio placentae, haemorrhage, emergency caesarean section, rupture of membranes (ROM); left ventricular ejection fraction, cardiomyopathy (CMP), arrhythmia, pulmonary hypertension, thromboembolic complications; hypertension, endocarditis and cardiomyopathy.
2. The set of fetal/neonatal outcomes listed in Appendix 3 of the protocol will consist of the following data: APGAR score, birth weight, length of stay, fetal mortality, reason for preterm birth, neonatal admission, neonatal mortality, intrauterine growth restriction (IUGR) and birth injury.

The registry will collect these data from the first consultation in a tertiary centre up to and including 12 weeks after delivery (cf. fourth trimester). For each enrolled pregnant woman, there will be at least 4 data collection points: at least 1 data collection point during the perinatal period, depending on the date of enrolment and the current gestational age (cf. trimester 1, 2 or 3) and at least 3 data collection points during the postpartum period (cf. week 1, 6 and 12 postpartum).

Figure 1 of the study protocol provides a visual overview of the respective data collection points for demographics and clinical outcomes. Figure 2 also provides a visual overview of the respective data collection points for the PROMS and PREMS datasets. It is important to note that the date of enrolment during the perinatal period is a highly variable element of the study, where the date of the patient's first registration at the outpatient clinic may vary between trimester 1, 2 or 3. During this perinatal period there will be at least one measurement time per participating patient. However, depending on the patient's exact enrolment date and gestational age, an attempt will be made to provide one data collection point per trimester. Ideally, however, the maximum number of measurement times (one measurement time per trimester) should be achieved, as shown in the figure.

Overall study start date
17/07/2023

Completion date
24/12/2025

Eligibility

Key inclusion criteria
1. Ongoing follow-up at the cardio-obstetrics/heart and women service at one of the participating centres
2. Pregnant women with congenital heart disease as defined by Mitchell et al, 1971; and/or acquired heart disease; and/or severe pre-existing hypertension; and/or cardiac arrhythmias (with or without the presence of an internal defibrillator); and/or a history of peripartum cardiomyopathy; and/or systemic diseases with cardiac burden.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
75

Key exclusion criteria
1. Pregnant women with pre-eclampsia/HELLP (haemolysis, elevated liver enzymes and low platelets) as a primary cardiovascular condition

Date of first enrolment
10/09/2023

Date of final enrolment
30/10/2025

Locations

Countries of recruitment
Belgium

Study participating centre
Antwerp University Hospital
Drie Eikenstraat 655
Antwerp
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2650

Study participating centre
Ghent University Hospital
Corneel Heymanslaan 10
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Sponsor information

Organisation
University of Antwerp

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Sponsor type
University/education

Website
https://www.uantwerpen.be/en/research-groups/centre-for-research-innovation-care/

ROR
https://ror.org/008x57b05

Funder(s)

Funder type
University/education

Funder Name
Universiteit Antwerpen

Alternative Name(s)
University of Antwerp, UAntwerp, Universiteit van Antwerpen, Uantwerpen

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Belgium

Results and Publications

Publication and dissemination plan
The results of this study will first be incorporated into a manuscript and prepared for peer-reviewed scientific publication, and then communicated to all panelists. In addition, the results of this study will provide more information on the relevant outcomes to monitor in pregnant women with CVD, which can be systematically incorporated into the follow-up of these patients.

Intention to publish date
10/10/2026

Individual participant data (IPD) sharing plan
Only people directly involved in the study will have access to personal information. Personal information will not be shared with anyone else. Also, no healthcare provider in the hospital will receive personal information from the trial without your consent. The researchers will keep study data for 20 years. Participants have the right to ask the researcher what information is being collected about them for this trial and why. As long as there is a link between their personal information and the personal code, they can ask for certain information to be corrected or deleted, or for their information not to be used. Once the data has been processed, participants' personal information will be deleted and it will no longer be possible to provide feedback.

All data collected from study participants will be treated in accordance with the 'Directive for the Protection of Individuals with regard to the Processing of Personal Data' and applicable national legislation. In addition, the European General Data Protection Regulation, the General Data Protection Regulation (AVG/GDPR - EU2016/679) and the Belgian legislation further elaborating this regulation will be respected during the conduct of this study.

The University Hospital Antwerp, as sponsor of the study, is responsible for processing the personal data of the participants. It has appointed a data processing officer for this purpose. Questions regarding the management of participants' data can be addressed to the Principal Investigator or to the Data Protection Officer of the University Hospital of Antwerp by e-mail: dpo@uza.be. If participants feel that their rights with regard to their personal data have not been sufficiently respected, they may at any time contact the Data Protection Officer, who will take the necessary measures. They also have the right to lodge a complaint with the Belgian Data Protection Authority: contact@apd-gba.be.

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Dr. Eva Goossens (eva.goossens@uantwerpen.be).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			08/11/2024	No	No
Other files			08/11/2024	No	No
Protocol file	version 2	21/05/2024	08/11/2024	No	No