INFORMATION SHEET FOR THE PATIENT

TITLE OF THE STUDY: MATERNAL AND NEONATAL OUTCOMES IN PLANNED HOMEBIRTHS ASSISTED BY MIDWIVES IN CATALONIA.

MAIN INVESTIGATOR: Dra.Gemma Robleda Font, PhD student Lucia Alcaraz-Vidal.
Mail contact: lucialcaraz1@gmail.com

CENTER: Investigation group Cuida2 Escuela Superior de Enfermería del Mar, Hospital de la Sta.Creu i St. Pau

INTRODUCTION

With the present, we wish to inform you about a research study in which you are invited to participate. The study has been approved by the Clinical Research Ethics Committee of Parc de Salut Mar.

We wish you to receive the correct and sufficient information to evaluate and judge whether you want to participate in this study. Therefore was ask you please to read this information sheet with attention and we will clarify any doubts that may arise after the explanation. In addition, you can ask for advice to anyone you might consider appropriate.

VOLUNTARY PARTICIPATION

You should know that your participation in this study is voluntary and that you can decide not to participate or change your decision and withdraw your consent at any time, without altering the relationship with your health provider nor causing any harm to your treatment.

GENERAL DESCRIPTION OF THE STUDY

The main aim of this study is to know if midwife-assisted home birth in Catalonia is safe, how the experience during childbirth is and what the costs are.

Therefore a first comparative study will be done, on childbirth safety for low risk pregnant women who have planned to given birth at home and at the collaborating hospitals. A second study will be done to know the experience of the users, and a third Study will be done aiming to calculate the cost of home birth in Catalonia and to compare it with hospital birth costs for low-risk women. With this purpose, a satisfaction survey will be used, among other instruments, which must be self-completed passed the first 15 days after childbirth. That is why that I request your collaboration. The survey is anonymous and self-administered and it consists of two parts. The first part are 18 questions to collect some personal data related to childbirth (e.g. age, country of origin, weeks of pregnancy, place of delivery) and the second is a validated questionnaire about the childbirth experience approaching 4 spheres in 22 questions: own capability, professional support, perceived safety and participation in the process. The questionnaire will be passed to 360 women and can be completed online or on paper.

Study Code: IIBS-PAR-2018-81

Version: 1 Date: 13/09/2018

For online completion, a contact e-mail will be requested. The approximate time required to complete it is 5 minutes.

BENEFITS AND RISKS DERIVED FROM YOUR PARTICIPATION IN THE STUDY

This study does not entail any risk for the participant's health; however, it will contribute to a better knowledge of the birth experience in Catalonia inside and outside the hospital.

This knowledge will serve as basis to improve care and to consider the implementation of new labour and childbirth care models.

CONFIDENTIALITY

The treatment, communication and transfer of all participants personal data will be in accordance with the legal current provisions, specifically: Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relating to the protection of Physical persons with regard to the processing of personal data, Organic Law 15/1999, December 13th, on Data Protection and Royal Decree 1720/2007, December 21th.

The data collected for the study will be identified by a code. Only the principal investigator and collaborating researchers will be able to relate your data to you. Therefore, your identity will not be disclosed to anyone unless required by law.

ECONOMIC COMPENSATION

Your participation in the study will not entail any expense or any economic benefit.

OTHER RELEVANT INFORMATION

If you decide to withdraw consent to participate in this study, no new data will be added to the database and you may demand the destruction of the questionnaire containing your answers.

You should also know that you could be excluded from the study if the study researchers consider it appropriate. In any case, you will receive an adequate explanation of the reason that caused your withdrawal from the Study.

By signing the enclosed consent form, you agree to comply with the procedures that have been exposed to you.