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Safety, experiences and economic cost of planned home birth in Catalonia

Submission date
14/10/2018

Recruitment status
No longer recruiting

Registration date
09/11/2018

Overall study status
Completed

Last Edited
13/12/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Recent studies show that planned home birth is a safe option for low-risk women. These studies look at different aspects: safety in terms of health problems for the mother and baby resulting from the birth, women's experiences of the birth and its economic costs. These three dimensions of childbirth care are measured comparing the birthplace chosen by women and the type of professional attending childbirth. These studies conclude that home birth is as safe as or even safer than hospital birth for women with straightforward pregnancies (without any risk factor until labour starts), it is a satisfactory experience and it is cost effective.
In Spain, planned home birth is a private service provided by midwives. More than one third of all annual Spanish home births take place in Catalonia. The Catalonian home birth midwives' association, Associació de llevadores de part a Casa de Catalunya (ALPACC), collects data in a database of all births planned at home with the associated midwives. This database will be one of the sources used for the first and third phases of this study.
This study is planned in 3 phases and aims to investigate if home birth with midwives in Catalonia is safe (phase 1), if it is a satisfactory experience (phase 2) and if it is sustainable (phase 3).

Who can participate?
Pregnant women aged between 18 and 40 years with normal or low-risk pregnancies.

What does the study involve?
Phase 1 will involve analysis of the ALPACC database by the researchers. For Phase 2, participants will be sent a questionnaire relating to their experience of the birth 15 to 30 days after they have given birth. For Phase 3, midwives will be sent a questionnaire to record the hours of work, cost of materials used and time spent in hospital for each birth.

What are the possible benefits and risks of participating?
Participating in this study has no benefits or risks for the participating women, as the care being studied is that routinely provided.

Where is the study run from?
Universitat Pompeu Fabra, Catalonia, Spain

When is the study starting and how long is it expected to run for?
January 2016 to June 2020

Who is funding the study?
The researchers are funding the study.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IIBSP-PAR-2018-81

Study information

Scientific Title
Maternal and neonatal outcomes on planned homebirth assisted by midwives in Catalonia: Cross-sectional study

Acronym
HomebirthCat I

Study objectives
Planned home birth for low-risk women assisted by midwives is safe, is a positive experience and has lower economic costs than hospital birth.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approval has been requested from the ethics committee of Parc de Salut Mar (CEIC PSMAR) and the ethics committee of Hospital de la Sta. Creu i St.Pau. Study Code: IIBS-PAR-2018-81

Study design
Observational multicenter cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Delivery

Interventions
For phase 1, the active participation of women will not be necessary; data will be collected from the databases.
Participants in phase 2 will be recruited in the hospital and at home after delivery to be informed and obtain informed consent. After 15 days postpartum, the questionnaire will be sent by mail or will meet with their midwife who will provide the questionnaire in paper form.
For phase 3, the active participation of women is not required; the questionnaire on costs will be completed by the midwife attending the birth.

Intervention Type
Behavioural

Primary outcome measure
Phase 1:
1. Composite rate of neonatal death during labour and early neonatal death assessed using the ALPACC database with a 7 days follow-up time after the birth
2. Composite rate of maternal death during labour and early maternal death assessed using the ALPACC database with a 7 days follow-up time after the birth
3. Rate of postpartum haemorrhage measured after birth using the ALPACC database
4. Rate of perineal injury measured after birth using the ALPACC database
5. Rate of women admitted in intensive care unit after birth to 24 h postpartum using the ALPACC database.
6. Rate of neonates with neonatal encephalopathy measured 7 days after birth using the ALPACC database
7. Rate of neonates with Apgar score equal to 7 or lower, measured after birth using the ALPACC

database.
8. Rate on neonates admitted into neonatal intensive care unit (NICU) from birth to 24 h after birth using the ALPACC database

Phase 2:
1. Women's perception of their own capacity during birth, assessed using the Childbirth Experience Questionnaire (CEQ-E), filled in between 30 days and 3 months after the birth
2. Women's perception of the professional support during birth, assessed using the CEQ-E, filled in between 30 days and 3 months after the birth
3. Women's perception of their safety during birth, assessed using the CEQ-E, filled in between 30 days and 3 months after the birth
4. Women's perception of their participation during birth, assessed using the CEQ-E, filled in between 30 days and 3 months after the birth

Phase 3: primary outcomes
1. Cost of labour and birth care measured using a questionnaire filled by midwives in the obstetric unit before discharge.
2. Human resources cost measured using a questionnaire filled by midwives in the obstetric unit before discharge
3. Material resources cost, measured using a questionnaire filled by midwives in the obstetric unit before discharge
4. Pain management cost, measured using a questionnaire filled by midwives in the obstetric unit before discharge
5. Structural costs, measured using a questionnaire filled by midwives in the obstetric unit before discharge

Secondary outcome measures
N/A

Overall study start date
01/01/2016

Completion date
31/05/2021

Eligibility

Key inclusion criteria
1. Pregnant women aged 18-40 years with straightforward pregnancy
2. Labour starting spontaneously between 37 and 42 weeks
3. Single foetus in cephalic presentation
4. Labour assisted by midwives

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
340

Key exclusion criteria
1. Women with diseases or medical conditions that could influence birth outcomes
2. Women with serious complications in previous pregnancies
3. Women without antenatal care
4. Women with a BMI higher than 35 kg/m2
5. Women planning hospital birth but delivering at home or while going to the hospital
6. Women planning childbirth in a freestanding birth centre
7. Women with premature rupture of membranes for more than 72 hours
8. Women with previous caesarean section
9. Women with prenatal congenital malformation diagnosis

Date of first enrolment
01/01/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
Spain

Study participating centre
Sant Pau Hospital, Barcelona
Sant Antoni Maria Claret, 167
Barcelona
Spain
08025

Study participating centre
Hospital Parc Salut Mar, Barcelona to Hospital Germans Trias i Pujol
Carretera del Canyes S/N
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/04n0g0b29

Funder(s)

Funder type
Other

Funder Name
Self funded

Results and Publications

Publication and dissemination plan
The first and second papers are going to to be published in 2019, with a third paper published in 2020.

Intention to publish date
01/03/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2021	13/12/2023	Yes	No
Results article		27/11/2023	13/12/2023	Yes	No