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Midwives' contribution to normal childbirth care: Cross-sectional study in public hospitals in Catalonia

Submission date
28/09/2015

Recruitment status
No longer recruiting

Registration date
11/12/2015

Overall study status
Completed

Last Edited
04/01/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
When a pregnant woman is fit and healthy, it is more likely that she will have a birth without complications that could affect the mother or child's health (normal birth). Studies have shown that there is a great variation in the care that women receive when they are in hospital giving birth. There is also a rising concern that this variability may affect the overall health of the babies that are born (birth outcomes), such as birth weight, or how far along in the pregnancy the mother was before giving birth (gestational age). This study will look at births taking place in public hospitals in Catalonia (Spain) in order to find out how many normal births are attended by midwives, and comparing this to birth outcomes.

Who can participate?
Healthy women between 18 and 40 years old with a single child pregnancy.

What does the study involve?
All of the participating hospitals register the information of women who attend the hospital to give birth and record the specific care that she receives during labour, delivery and shortly after birth. The number of births attended by midwives is recorded, as well as recording birth outcomes (health of the baby at the time of birth).

What are the possible benefits and risks of participating?
There are no direct benefits or risks for participants taking part in the study.

Where is the study run from?
Hospital General de l'Hospitalet (lead centre) and 12 other public hospitals in Catalonia (Spain)

When is the study starting and how long is it expected to run for?
September 2015 to December 2017

Who is funding the study?
Catalonia Nurses Colleges Council (Spain)

Who is the main contact?
Dr Ramón Escuriet

Study website
www.llevadora.eu

Contact information

Type(s)
Scientific

Contact name
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Barcelona
Spain
08006

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
MIDwives CONtribution to childbirth care provision versus other health professionals childbirth care provision and BIRTH outcomes in public hospitals in Catalonia

Acronym
MIDCONBIRTH

Study objectives
The aim of this study is to find out the proportion of normal births attended to by midwives in public hospitals in Catalonia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité Ético de Investigación Clínica del Consorci Sanitari Integral, 16/12/2015, ref: 15/74

Study design
Prospective multi-centre cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

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

Interventions
In this study the intervention considered is the care provided to low risk women during labour, delivery and early postpartum period. This intervention includes all procedures performed during the intrapartum care process. For that purpose, the health professional profile attending to the woman and data related to diagnoses and procedures performed to each woman who meet inclusion criteria will be registered. Each participating hospital will register data from all low risk women being admitted for labour during a four months period or until a representative sample is achieved for each hospital, according to the annual volume of births attended to in the hospital. Participating hospitals will be progressively included during the study period until June 2017.

Intervention Type
Other

Primary outcome measure
Percentage of low risk births attended to by midwives in public hospitals in Catalonia during the study period.

Secondary outcome measures
Outcomes of births attended to by midwives, measured using Bologna Score within 24 hours after birth and before discharge from maternity ward.

Overall study start date
18/09/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Aged between 18 and 40 years
2. Female participants
3. Singleton pregnancy
4. Cephalic presentation of the foetus
5. Labour between 37 and 42 weeks gestation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Total recruitment: 1434

Total final enrolment
11537

Key exclusion criteria
1. High or very high risk during pregnancy
2. Newborn Congenital disease detection after childbirth

Date of first enrolment
01/12/2015

Date of final enrolment
01/06/2017

Locations

Countries of recruitment
Spain

Study participating centre
Hospital General de l'Hospitalet
Av. Josep Molins, 29-41
L'Hospitalet De Llobregat

Barcelona
Spain
08906

Study participating centre
Hospital Parc Taulí de Sabadell
Parc Taulí, 1
Sabadell
Barcelona
Spain
08208

Study participating centre
Hospital Sant Joan de Déu de Manresa
Manresa
Barcelona
Spain
08243

Study participating centre
Fundació Hospital Sant Joan de Déu de Martorell
Av. Mancomunitat Comarcals, 1-3
Martorell
Barcelona
Spain
08760

Sponsor information

Organisation
Catalonia Nurses Colleges Council (Consell de Col·legis d'Infermeres i Infermers de Catalunya)

Sponsor details
Carrer Rosselló, 229
Barcelona
Spain
08008

Sponsor type
Other

Funder(s)

Funder type
Government

Funder Name
Catalonia Nurses Colleges Council

Results and Publications

Publication and dissemination plan
1. A general report with all relevant results will be elaborated
2. Congress contributions (poster and communications)
3. At least one paper will be submitted to an international journal (preferably Q1 Journal)

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
Not provided at the time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/11/2021	13/12/2021	Yes	No
Interim results article		13/11/2020	04/01/2023	Yes	No