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Midwives' contribution to normal childbirth care. Cross-sectional study in public health settings

Submission date
14/10/2016

Recruitment status
No longer recruiting

Registration date
19/10/2016

Overall study status
Completed

Last Edited
18/11/2024

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
Recent research suggests that there is some variability in the care that is given to women and their babies during labour and immediately after birth (intrapartum care). Intrapartum care can include recommendations on where the baby should be delivered, pain relief during labour, care given in the first, second and third stages of labour and care of mother and baby after the birth. Variability in intrapartum care raises concerns about how this may impact on the health of some mothers and newborn babies. This study is looking at how many normal births are attended by midwives in public health settings (for example, hospitals) and at home and recording what happens during the birth and shortly afterwards.

Who can participate?
Women aged between 18-40 pregnant with one baby and about to give birth.

What does the study involve?
This study looks at the care provided for all participants during their labour, delivery of their baby and the care of themselves and their baby after the birth. Information on all participants is recorded by the attending midwife over a 4 month period, or until a representative sample of data is collected for each type of setting that a baby can be born (that is, hospital, birth centre or whether the baby is born at home with the help of a midwife).

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

Where is the study run from?
Four different hospitals in Spain.

When is the study starting and how long is it expected to run for?
October 2016 to December 2019

Who is funding the study?
Catalonia Council of Nurses

Who is the main contact?
Dr Ramón Escuriet

Study website
www.llevadora.eu

Contact information

Type(s)
Scientific

Contact name
Dr Ramón Escuriet

ORCID ID
http://orcid.org/0000-0002-7277-3331

Contact details
Doctor Aiguader, 80, 3ª Planta (Despatx 61.311)
Barcelona
Spain
08003

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016/6785/I

Study information

Scientific Title
MIDwives CONtribution to childbirth care provision versus other health professionals childbirth care provision and BIRTH outcomes in public health settings (Second Phase of Midconbirth study)

Acronym
MIDCONBIRTH II

Study objectives
This study will find out the proportion of normal births attended to by midwives in public health settings in Spain and in other European participating countries

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committees of Clinical Research (Comité de Ética de Investigación Clínica del Parc Salut Mar), 25/05/2016, ref: 2016/6785/I

Study design
Prospective multicentre and cross-sectional study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
See additional files

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

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 setting or midwife 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 setting (hospital, birth center or home birth midwife, according to the annual volume of births attended to in the setting or by the participating midwife. Participating settings and midwives will be progressively included during the study period until June 2019

Intervention Type
Other

Primary outcome measure
Percentage of low risk births attended to by midwives in public health settings and publicly funded home births during the study period. Measure will consist in the identification of the health professional providing care and attending the delivery for each woman .

Secondary outcome measures

1. Outcomes of births attended to by midwives, measured using Bologna Score within the 24 hours after birth and before discharge from maternity ward
2. Transfer rates from public birth centres and home births attended to by midwives to obstetric units

Overall study start date
01/10/2016

Completion date
01/12/2019

Eligibility

Key inclusion criteria
1. Women aged 18 years or older
2. Women aged 40 years or younger
3. Singleton pregnancy
4. Cephalic presentation of the foetus
5. Not classified as women at high or very high risk during pregnancy
6. Starting labour from 37 (first day) weeks of pregnancy and before 41 (last day) weeks of pregnancy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1500

Total final enrolment
5497

Key exclusion criteria
1. Women Aged 17 years or younger
2. Women Aged 41 years or older
3. No singleton pregnancy
4. No cephalic presentation of the foetus
5. Classified as women at high or very high risk during pregnancy
6. Starting labour before 36 [last day (36 w + 6 days)) weeks of pregnancy and at or after 42 weeks of pregnancy
7. Newborn Congenital disease detection after childbirth

Date of first enrolment
01/10/2016

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
Ireland

Italy

Spain

Switzerland

United Kingdom

Study participating centre
Hospital del Mar. Parc de Salut Mar
Doctor Aiguader, 80, 3ª Planta
Barcelona
Spain
08003

Study participating centre
Hospital Costa del Sol de Málaga
Autovia A-7, Km 187
29603 Marbella
Málaga
Spain
29603

Study participating centre
Hospital Rio Hortega de Valladolid
Calle Dulzaina, 2
Valladolid
Spain
47012

Study participating centre

Hospital de La Marina Baixa de Villajoyosa
Avenida Alcalde En Jaume Botella Mayor, 7
La Vila Joiosa
Alicante
Spain
03570

Sponsor information

Organisation
Catalonia Council of Nurses

Sponsor details
Carrer del Rosselló, 229,
Barcelona
Spain
08008

Sponsor type
Not defined

Funder(s)

Funder type
Government

Funder Name
Catalonia Council of Nurses

Results and Publications

Publication and dissemination plan
1. A general report of all results will be made (end of 2019)
2. Congress contributions (poster and communications)
3. Al least one paper will be submitted to an international journal during 2019 (preferably Q1 Journal)

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan

Please contact ; Dr. Ramón Escuriet (rescuriet@me.com) or Catalonia Council of Nurses (consell@codinf.org) for access

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		19/10/2016	21/10/2016	No	Yes
Results article	results	01/03/2019	12/02/2021	Yes	No
Results article	Oxytocin Administration in Low-Risk Women, a Retrospective Analysis of Birth and Neonatal Outcomes	20/04/2021	18/11/2024	Yes	No