ISRCTN14256563 https://doi.org/10.1186/ISRCTN14256563

Satisfaction in women who have recently given birth receiving epidural analgesia after shared-decision making before the onset of labor

Submission date
01/04/2020

Recruitment status
No longer recruiting

Registration date
15/04/2020

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Epidural analgesia is the administration of opioids and/or local anesthetics into the epidural space. It is often administered during childbirth.
The clinical explanation of epidural analgesia by anesthesiologist would often begin after the pregnant mother (parturient) is admitted into the hospital. However, because of labor pain, the decision of receiving epidural analgesia would often be made by the companion of the parturient, such as the husband, instead of the parturient herself. The researchers believe that this situation should be remedied and thus conducted a study comparing the satisfaction and level of epidural analgesia comprehension in parturients receiving the routine procedure and those receiving a prenatal shared decision-making (SDM) intervention.

Who can participate?
Women who have recently given birth by natural spontaneous delivery who used epidural analgesia during the natural birth process

What does the study involve?
During their 28th week of gestation, the SDM group is given a health education leaflet with a QR codelinking to health education videos that explain what epidural analgesia is and its advantages and disadvantages. After giving birth patients answer a questionnaire.

What are the possible benefits and risks of participating?
After the intervention, participation in decision-making may improve. There is no risk in participating in this trial.

Where is the study run from?
Chi Mei Medical Center (Taiwan)

When is the study starting and how long is it expected to run for?
June 2018 to December 2019

Who is funding the study?
This study was supported by Chi Mei Medical Center (Taiwan), under the grant CMFHR108110.

Who is the main contact?
Dr Ying-Jen Chang, 0201day@yahoo.com.tw

Contact information

Type(s)
Scientific

Contact name
Dr Ying-Jen Chang

ORCID ID
https://orcid.org/0000-0002-4824-6216

Contact details
Department of Anesthesiology
Chi Mei Medical Center
901 Zhonghua Road
Yongkang District
Tainan
Taiwan
710
+886 62812811
cmh7760@mail.chimei.org.tw

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
IRB Serial No.: 10705-010

Study information

Scientific Title
Evaluating the satisfaction in parturients receiving epidural analgesia after prenatal shared decision-making intervention

Study objectives
The satisfaction and level of epidural analgesia comprehension will improve in parturients receiving the routine procedure and those receiving a prenatal shared decision-making (SDM) intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved DATE, Institutional Review Board of the Chi Mei Medical Center (901 Zhonghua Road, Yongkang District, Tainan, 701, Taiwan R.O.C.; +886-6-281-2811-53720; cmhirb@mail.chimei.org.tw), ref: 10705-010

Study design
Interventional non-randomised before and after study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Epidural analgesia during childbirth

Interventions
During their 28th week of gestation, the shared decision making (SDM) group was given a health education leaflet with a QR codelinking to health education videos that explained what epidural analgesia is and its advantages and disadvantages. A specific questionnaire in local language (Chinese)—designed to measure the satisfaction of labor pain relief, the degree of access to information, and the communication from health care staff—incorporated items from three health care communication questionnaires: Pregnancy and Maternity Care Patients' Experiences Questionnaire (PreMaPEQ), Preterm Birth Experience and Satisfaction Scale (P-BESS), and Women's Views of Birth Labor Satisfaction Questionnaire (WOMBLSQ).

Intervention Type
Behavioural

Primary outcome(s)
Satisfaction measured using a novel questionnaire combining elements of Pregnancy and Maternity Care Patients' Experiences Questionnaire (PreMaPEQ), Preterm Birth Experience and Satisfaction Scale (P-BESS), and Women's Views of Birth Labor Satisfaction Questionnaire (WOMBLSQ) after giving birth.

Key secondary outcome(s))
Comprehension of the consenting process measured using a novel questionnaire combining elements of Pregnancy and Maternity Care Patients' Experiences Questionnaire (PreMaPEQ), Preterm Birth Experience and Satisfaction Scale (P-BESS), and Women's Views of Birth Labor Satisfaction Questionnaire (WOMBLSQ) after giving birth.

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Parturients after natural spontaneous delivery who have used epidural analgesia during the natural birth process

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
200

Key exclusion criteria
1. Mental disorders or emotional disorders, regardless of whether they are receiving psychiatric medication
2. Drug addiction or drug dependence (for example, those who have a history of drug use, or who have used morphine analgesics daily for more than 30 mg of oral morphine equivalent for more than six weeks)
3. Cannot read Chinese
4. In the intensive care unit after delivery

Date of first enrolment
14/06/2018

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Taiwan

Study participating centre
Chi Mei Medical Center
901 Zhonghua Road
Yongkang District
Tainan
Taiwan
710

Sponsor information

Organisation
Chi Mei Medical Center

ROR
https://ror.org/02y2htg06

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chi Mei Medical Center

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Taiwan

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/07/2020	22/07/2020	Yes	No
Dataset	The raw data of the 200 file-questionnaires.		12/06/2023	No	No