

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

<b>Submission date</b> 01/04/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/04/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/06/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input checked="" type="checkbox"/> 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

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

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

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# 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?
<a href="#">Results article</a>	results	20/07/2020	22/07/2020	Yes	No
<a href="#">Dataset</a>	The raw data of the 200 file-questionnaires.		12/06/2023	No	No