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Influence of prone position on a stretcher for pregnant women

Submission date
22/05/2016

Recruitment status
No longer recruiting

Registration date
01/07/2016

Overall study status
Completed

Last Edited
18/08/2023

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
As the volume of the abdomen increases during pregnancy, lying belly down is increasingly difficult and uncomfortable, so we have developed a special stretcher so that the pregnant woman can remain in that position during any stage of pregnancy. The stretcher has a hole in it, support for the head and a convex shape (half-moon) to improve back relaxation. As such a stretcher did not exist before this study, we wish to confirm whether placing the pregnant woman lying belly down would cause any problems in terms of heart rate, respiratory (breathing) rate, blood pressure and discomfort, and also to check the heart rate of their babies.

Who can participate?
Healthy pregnant and non-pregnant women aged between 20 and 34

What does the study involve?
Participants are randomly allocated to lie in one of two sequences of positions on the prototype stretcher. In each position we measured the participants' heart rate, respiratory (breathing) rate, blood pressure and any discomfort, and the heart rate of the babies.

What are the possible benefits and risks of participating?
In the future this stretcher could be used for pregnant women undergoing spinal surgery or for a physiotherapy session. The possible benefits for them would be feeling comfortable because this stretcher improves back relaxation and oxygenation.The possible risks would be the pregnant woman reporting discomfort or pain during positioning with some changes of normal values in heart rate, respiratory rate and blood pressure.

Where is the study run from?
Department of Obstetrics, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, SP, Brazil

When is the study starting and how long is it expected to run for?
April 2012 to March 2013

Who is funding the study?
Department of Obstetrics, Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, SP, Brazil

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
N/A

Study information

Scientific Title
Influence of prone position on a stretcher for pregnant women in maternal and fetal hemodynamic parameters and comfort of the pregnant woman

Study objectives
Due to the increase of the abdominal volume, the prone position is a difficult and uncomfortable position for pregnant women. Hence, so far, it has not been tested if, in this position, a pregnant woman would have her maternal fetal hemodynamic parameters altered. The present study aims to analyze the influence of the prone position in maternal-fetal hemodynamic parameters and

the comfort of the pregnant woman on a prototype stretcher specially built for pregnant women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee Hospital das Clinicas - Universidade de São Paulo, 13/03/2012, Ref: 0843-11

Study design
Randomized cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Maternal and fetal hemodynamic parameters

Interventions
After collecting the sociodemographic data, the women were asked to lie in each of the following positions on the special stretcher for 6 minutes: supine position (SP) with a 15-degree tilt, left lateral (LL) position with support for the lower limbs, prone position (PP) with a cervical support in the stretcher, and Folwer position (FP), i.e., semi-upright with slightly flexed knees and a 45° support placed behind the back.

The participants in the pregnant group (PG) and the non-pregnant group (NPG) were divided into two subgroups depending on the order of the patients' positions on the special stretcher: PGS1 (pregnant group sequence one); PGS2 (pregnant group sequence two), NPGS1 (non-pregnant group sequence one) and NPGS2 (non-pregnant group sequence two).

We defined two types of position sequences. Sequence 1 was FP, PP, SP, LL, FP, SP, PP and LL, and sequence 2 was FP, PP, LL, SP, FP, LL, PP and SP. The patients were randomized to perform sequence 1 or 2 (the randomization list was created on 03/04/2012). The order of the components of these two sequences was changed eight times to determine whether the order produced any significant variations in the following parameters in the PG and NPG patients: heart rate (HR), oxygen saturation (SpO2), systolic blood pressure (SBP), diastolic blood pressure

(DBP) and respiratory rate (RR). In addition, any significant variations in the baseline fetal HR and fetal variability indexes in the PG in response to changing the order of the sequences was determined.

All volunteers were analyzed in a single moment. Each participant was asked to lie on the special stretcher, where they remained in a sitting position for 10 minutes to stabilize the hemodynamic parameters in a calm environment with a mild temperature. All of the women and fetuses were monitored during this process.

Intervention Type
Other

Primary outcome measure
1. The maternal hemodynamic indexes:
1.1. Heart rate (HR)
1.2. Oxygen saturation (SpO2)
1.3. Systolic blood pressure (SBP)
1.4. Diastolic blood pressure (DBP)
1.5. Respiratory rate (RR)
Measured using a multiparameter monitor Dixtal, model DX-2020- Campinas-São Paulo-Brazil. The methodology was standardized, and the tensional levels were measured in the left upper arm. The cuff was placed 2.5 cm above the antecubital space. The RR was timed in 1 minute of respiratory cycles (inspiration and expiration).

2. The fetal parameters, such as the fetal HR and uterine contractions, were assessed by fetal cardiotocography performed using non-stress test equipment, model Bistos nº 049-Ribeirão Preto-São Paulo-Brazil.

Secondary outcome measures
Maternal comfort: before shifting to the next position, each participant answered the following questions: Are you comfortable? Have you felt any discomfort in this position? All of the assessments were performed by the same researcher. The simple answer of yes or no was used.

Overall study start date
05/04/2012

Completion date
10/03/2013

Eligibility

Key inclusion criteria
1. Healthy pregnant women between 20 and 34 years of age with singleton pregnancies
2. Gestational age between 20 and 37 weeks
3. No evidence of spinal disease
4. Healthy patients as the non-pregnant women

Participant type(s)
Healthy volunteer

Age group

Adult

Lower age limit
20 Years

Upper age limit
34 Years

Sex
Female

Target number of participants
30 pregnant and 16 non-pregnant women

Total final enrolment
33

Key exclusion criteria
Presence of pain and/or discomfort on the special stretcher

Date of first enrolment
05/04/2012

Date of final enrolment
10/03/2013

Locations

Countries of recruitment
Brazil

Study participating centre
Universidade de São Paulo
Department of Obstetrics
Hospital das Clínicas da Faculdade de Medicina
Avenida Doutor Enéas de Carvalho Aguiar, 255; 10° Andar
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Sponsor information

Organisation
Universidade de São Paulo (Brazil)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/036rp1748

Funder(s)

Funder type
University/education

Funder Name
Universidade de São Paulo

Alternative Name(s)
University of São Paulo, USP

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Brazil

Results and Publications

Publication and dissemination plan
We are planning to publish the results in June 2016

Intention to publish date
01/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/07/2016		No	No
Results article		01/06/2017	18/08/2023	Yes	No