Comparison effect of chewing flavourless and flavored with mint gum on stress and anxiety the first stage of labor in nulliparous women

Protocol summary

Summary
Objectives: To investigate the Comparison effect of chewing flavourless and flavored with mint gum on stress and anxiety the first stage of labor in nulliparous women. Design: This is a randomized clinical trial on 90 nulliparous women that will be randomly assigned in 2case group(n=60) and control group(n=30). Setting and conduct: This study will be carried out in Ommol Banin hospital, Mashhad city. At the beginning of study for all subjects questionnaire demographic, family, labor, fatigue, hunger and perceived stress scale completed and Spielberger state-trait will be completed for all subjects and Saliva samples were taken to measure the stress. After 20 minutes of chewing gum in the 2case group, all variables will be measured for all subjects. Participations including major eligibility criteria: All nuliparou 18 to 35 years old women with a singleton term pregnancy in active phase of labor in 7-5 cm dilatation will be included the study. Intervention: A sugar-free smile gum from will be used for 1case group and A sugar-free mint gum from will be used for 2case group. No intervention was performed in the control group. Main outcome measures variables: saliva cortisol level, anxiety level

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2013011312108N1
Registration date: 2013-02-09, 1391/11/21
Registration timing: registered_while_recruiting

Last update: 
Update count: 0
Registration date
2013-02-09, 1391/11/21

Registrant information
Name
Seide Fateme Alavian
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source
Mashhad University of Medical Sciences

Expected recruitment start date
2012-12-25, 1391/10/05
Expected recruitment end date
2013-04-25, 1392/02/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison effect of chewing flavourless and flavored with mint gum on stress and anxiety the first stage of labor in nulliparous women

Public title
Comparison effect of chewing flavourless and flavored with mint gum on stress and anxiety the first stage of labor in nulliparous women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Gestational age of 42-37 weeks ; presence of at least 18 natural teeth in a good state of repair with the ability to chew gum for at least 20 min at a time; Refrain from eating 1hourse before preparation of saliva samples; 5-7 cm of cervical dilatation Exclusion criteria: History of Medical and psychological disorders; Very mild or severe anxiety and stress; Extreme hunger and fatigue; Obstetric problems; Develop symptoms of fetal distress Lack of saliva 5-3 ml.

Age
From 18 years old to 35 years old

Gender
Female
Phase
N/A

Groups that have been masked
None

Sample size
Target sample size: 90

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary IDs
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Building Qureshi, University Street
City
Mashhad
Postal code
91375-345
Approval date
2012-12-24, 1391/10/04
Ethics committee reference number
511/3659

Health conditions studied

1
Description of health condition studied
Stress and anxiety in labor
ICD-10 code
F43.1, F41.
ICD-10 code description
Anxiety disorder, unspecified and Acute stress reaction

Primary outcomes

1
Description
Stress active phase of labor
Timepoint
Before and after intervention
Method of measurement
Salivary cortisol

Secondary outcomes
empty

Intervention groups

1
Description
Chewing of sugar-free orbit mint gum for 20 minutes in 5-7 cm of cervical dilatation
Category
Other

2
Description
Chewing of sugar-free flavourless gum for 20 minutes in 5-7 cm of cervical dilatation
Category
Other

3
Description
No intervention in the control group
Category
N/A

Recruitment centers

1
Recruitment center
Name of recruitment center
Ommol Banin Hospital
Full name of responsible person
Fatemeh Tara
Street address
Behjat street
City
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Building Qureshi, University Street
City
Mashhad
Grant name
معاونت پژوهشی دانشگاه علوم پزشکی مشهد
Grant code / Reference number
910667
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
empty
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Parvin Salari
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Web page address

Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty