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 2 case 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 2 case group, all variables will be measured for all subjects. Participations including major eligibility criteria: All nulliparous 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 1 case group and A sugar-free mint gum from will be used for 2 case 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

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 1 hour 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
Mashhad

**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

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**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**
Mashhad University of Medical Sciences

**Full name of responsible person**
Parvin Salari

**Position**
Master of Midwifery

**Other areas of specialty/work**

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Ebne Sina Street, University Street

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**Person responsible for updating data**

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Seiede Fateme Alavian

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Student mastre of midwifery

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**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