Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of sugar free chewing gum on labor anxiety and plasma Cortisol levels in nulliparous women

Protocol summary

Summary

Objectives: To investigate the effect of sugar-free chewing gum on labor anxiety and plasma cortisol levels. Design: This is a randomized clinical trial on 80 nulliparous women that will be randomly assigned in case group(n=40) and control group(n=40). Setting and conduct: This study will be carried out in Razi hospital, Ahvaz city. At the beginning of study systolic and diastolic blood pressure, pulse rate and plasma cortisol levels will be measured at intervals of uterine contractions and Spielberger state-trait will be completed for all subjects. In this questionnaire anxiety score is between 20 to 80. The scores between 20 to 49 and 50 to 80 are related to low and high anxiety levels, respectively. After 30 minutes of chewing gum in the case group, all variables will be measured for all subjects. Participations including major eligibility criteria: All nuliparou18 to 35 years old women with a singleton term pregnancy in active phase of labor will be included the study. Intervention: A sugar-free Orbit gum from Wrigley factory will be used for case group. No intervention was performed in the control group. Main outcome measures variables: Systolic and diastolic blood pressure, pulse rate, plasma cortisol level, anxiety level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109232204N2**
Registration date: **2011-10-03, 1390/07/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-10-03, 1390/07/11

Registrant information

Name

Somayeh Makvandi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2011-10-07, 1390/07/15

Expected recruitment end date

2012-02-04, 1390/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sugar free chewing gum on labor anxiety and plasma Cortisol levels in nulliparous women

Public title

The effect of chewing gum on anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-35; Gestational age between 37 to 42 weeks based on LMP or sonography under 26 weeks; Singleton fetus; Vertex presentation; 3-4 cm of cervical dilatation Exclusion criteria: Vaginal bleeding; Abnormal fetal heart rate; Abnormality or death of fetus;

Use of narcotic or anodyne drug or other pain reliever methods; Corporation in pre-labor education classes; History of psychological disorders; The recent death of a family member; Divorced women; Any history of chronic diseases

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Ahvaz Jundishapour University of Medical Sciences

Street address

Golestan highway

City

Ahvaz

Postal code

Approval date

2011-07-23, 1390/05/01

Ethics committee reference number

ETH-209

Health conditions studied

1

Description of health condition studied

Anxiety levels

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

anxiety level of active phase of labor

Timepoint

30 min after intervention

Method of measurement

Spielberger state-trait

2

Description

plasma Cortisol levels

Timepoint

30 min after intervention

Method of measurement

Blood sample

3

Description

pulse rate

Timepoint

30 min after intervention

Method of measurement

examination

4

Description

Systolic BP

Timepoint

30 min after intervention

Method of measurement

examination

5

Description

Diastolic BP

Timepoint

30 min after intervention

Method of measurement

examination

Secondary outcomes

1

Description

duration of active phase of labor

Timepoint

at the end of study

Method of measurement

observation

2

Description

duration of second stage of labor

Timepoint

at the end of study
Method of measurement
observation

3

Description
mood of delivery
Timepoint
at the end of study
Method of measurement
observation

4

Description
oxytocin volume
Timepoint
at the end of study
Method of measurement
observation

Intervention groups

1

Description
Chewing of sugar-free Orbit gum for 30 minutes in the case group
Category
Prevention

2

Description
No intervention in the control group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Shirin Zargar
Street address
Felestin Street
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahvaz Jundishapour University of Medical Sciences
Full name of responsible person
Mostafa Feqhi
Street address
Golestan highway
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Ahvaz Jundishapour 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
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Ahvaz Jundishapour University of Medical Sciences
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Person responsible for updating data

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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