

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

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**

Last update:

Update count: **0**

Registration date

2013-02-09, 1391/11/21

Registrant information

Name

Seiede Fateme Alavian

Name of organization / entity

Mashhad university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 1515

Email address

alavianf891@mums.ac.ir

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

No information

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 andAcute stress reaction

Primary outcomes

1

Description

Stress active phase of labor

Timepoint

Before and after interventiom

Method of measurement

Salivary cortisol

2

Description

Anxiety level of active phase of labor

Timepoint

Before and after intervention

Method of measurement

Spielberger state-trait

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

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

Position

Master of Midwifery

Other areas of specialty/work

Street address

Ebne Sina street ,University Street

City

Mashhad

Postal code

9137913199

Phone

+98 51 1859 1515

Fax

+98 51 1859 7313

Email

salarip@mums.ac.ir

Web page address

Person responsible for scientific 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

Street address

Ebne Sina Street, University Street

City

Mashhad

Postal code

9137913199

Phone

+98 51 1859 1515

Fax

+98 51 1859 7313

Email

salarip@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seiede Fateme Alavian

Position

Student mastre ofmidwifery

Other areas of specialty/work

Street address

Ebne Sina street, Univercity street

City

Mashhad

Postal code

9137913199

Phone

+98 51 1895 1515

Fax

+98 51 1895 7313

Email

alavianf891@mums.ac.ir

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