

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

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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
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Position
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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