Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of chewing gum on the severity of labor pain in primiparous women

Protocol summary

Study aim
Determining the effect of chewing gum on the severity of labor pain in primiparous women

Design
A clinical trial with a control group, with parallel groups, design (Open label), randomized, on 116 mothers in natural childbirth. Stata version 15 software was used for randomization.

Settings and conduct
In the maternity department of Yahiinejad and Ayatollah Rouhani Hospital, Babol, using a random list, mothers were assigned to the intervention and control groups. The control group received the necessary care and training for hospitalization, and the intervention group received sugar-free gum (at least twice for 20 minutes) used. Questionnaires of pain intensity and anxiety in two groups were filled by the participant in the active phase of labor

Participants/Inclusion and exclusion criteria
All the clients admitted to the Yahya Nejad and Ayatollah Rouhani Babol maternity ward before the start of the intervention were considered based on the evidence of nearly 116 people who met the study entry criteria. Inclusion criteria: Primiparous women with a gestational age of 38-42 weeks and presenting with cephalic... and exclusion criteria for the study Abnormal heartbeat of the fetus and unwillingness to continue cooperation...

Intervention groups
In the intervention group Sugar-free gum was given to patients by midwives on admission to ensure that all patients used the same gum. The gum of choice was unflavored and sugar-free: a generic brand found in any store that had no nutritional value (no fat, carbohydrates, or protein). The safety of the gum was guaranteed by the Food and Drug Administration. The load was performed in the active mode (dilation of 3-4cm), second (5-7cm) and third(8-10cm) in each stage of labor for 20 minutes. in the control group Routine prenatal care and emphasis on not using gum during labor

Main outcome variables
Primary outcome: labor pain Secondary outcome: anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100510003902N5**
Registration date: **2024-08-17, 1403/05/27**
Registration timing: **retrospective**

Last update: **2024-08-17, 1403/05/27**
Update count: **0**

Registration date
2024-08-17, 1403/05/27

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-01, 1400/02/11

Expected recruitment end date
2022-10-20, 1401/07/28

Actual recruitment start date
2021-05-01, 1400/02/11

Actual recruitment end date
2022-10-20, 1401/07/28
Trial completion date
2022-10-20, 1401/07/28

Scientific title
The effect of chewing gum on the severity of labor pain in primiparous women

Public title
The effect of chewing gum on the severity of labor pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous women with a gestational age of 38-42 weeks based on LMP or ultrasound less than 26 weeks Pregnant women whose labor started spontaneously Live pregnancy A singleton fetus Having consent to enter the study Pregnant women without any complications that may cause dystocia during childbirth. Able to chew gum Cephalic presentation
Exclusion criteria:
Women with chronic diseases vaginal bleeding Abnormal heartbeat of the fetus fetal abnormality Use of anesthesia and anesthesia in the first stage of childbirth Using other methods of childbirth analgesia History of mental illness (depression and stress) The recent death of a family member A history of a problem in one of the person's relatives due to natural childbirth drug use by the mother mother of a professional athlete Unwillingness to continue cooperation
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **116**
Actual sample size reached: **116**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Our sample size was 116 people, of which 58 people were placed in each group. The block random allocation method was designed by the project collaborator using Stata version 15 software. The number of considered blocks is 6. The concealment process of random assignment (Concealment): The list of random allocation of patients was only available to the collaborator of the project. In order to hide the random allocation process, the order of treatments was written on 116 cards based on the randomized list, and only the project associate was aware of the relevant coding. When the obstetrician and gynecologist announced the eligibility of a patient, the colleague will provide the plan for the type of interventions for the primiparous mother. Blinding: Due to the treatment methods of the two groups, blinding is not possible and the design is open label. In order to analyze the data, a statistician who is separate from the study process and is unaware of all the performed processes was used.
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
Babol University of Medical Sciences (Biomedical Research Ethics Committee)
Street address
Babol University of Medical Sciences, Ganj Afrooz St, Babol, Mazandaran
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Postal code
4717647745
Approval date
2021-05-01, 1400/02/11
Ethics committee reference number
IR.MUBABOL.HRI.REC.1400.059

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
Anxiety di
ICD-10 code description
F41.9

2

Description of health condition studied
labor pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Primary outcome: labor pain

Timepoint
before the start of the intervention, in the latent phase (3-4 cm), in the active phase (5-7 cm) and the transfer phase of the librarian (8-10 cm) after chewing the gum.
Method of measurement
Form VAS for participants

Secondary outcomes

1

Description
anxiety
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Spielberger questionnaire

Intervention groups

1

Description
Intervention group: Chewing gum was done three times in the active state (expansion of 3-5 cm), the second (expansion of 5-7 cm) and the third time of expansion of 8-10 cm) each stage of labor was performed for 20 minutes.
Category
Treatment - Other

2

Description
Control group: In the control group, routine prenatal care and emphasis on not using gum during labor
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospitals (Yahinejad and Rouhani) covered by Babol University of Medical Sciences
Full name of responsible person
Farideh Mohsenzade Ledari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Farideh Mohsenzadh Ledari
Position
Assistant Professor of Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available